

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 7, 2025

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BOBBIE SHOLDEBRAND,	*	PUBLISHED
	*	
Petitioner,	*	No. 18-1368V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Hepatitis B (“Hep B”) Vaccine;
	*	Tension Headaches; New Daily Persistent
	*	Headaches (“NDPH”); Cervicogenic
Respondent.	*	Headaches.
	*	

\* \* \* \* \*

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

**DECISION<sup>1</sup>**

On September 7, 2018, Bobbie Sholdebrand<sup>2</sup> (“Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. § 300aa-10 et seq. (2018),<sup>3</sup> alleging that she suffered “neck pain and loss

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<sup>1</sup> Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims’ website and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc> in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> The spelling of Petitioner’s last name was corrected in April 2019. Order dated Apr. 18, 2019 (ECF No. 12).

<sup>3</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) (“Vaccine Act” or “the Act”). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

of range of motion” as a result of receiving Hepatitis B (“Hep B”) vaccinations<sup>4</sup> administered on April 6, 2016 and May 18, 2016. Petition at 1-2 (ECF No. 1). Respondent argued against compensation, stating the case was “not appropriate for compensation under the terms of the [Vaccine] Act.” Respondent’s Supplemental Report (“Resp. Supp. Rept.”) at 2 (ECF No. 36).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards,<sup>5</sup> the undersigned finds Petitioner failed to provide preponderant evidence that the Hep B vaccines caused her alleged injuries (tension headaches or New Daily Persistent Headaches (“NDPH”)).<sup>6</sup> Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is not entitled to compensation.

## I. ISSUES TO BE DECIDED

In the parties’ joint submission, Respondent concedes Petitioner received Hep B and Tdap vaccinations on April 6, 2016 but disputes diagnosis and causation. Joint Pre-Hearing Statement of Facts (“Joint Submission”), filed Sept. 19, 2023, at 1 (ECF No. 102).

Regarding diagnosis, Petitioner alleges her injury is tension headaches, noting that both of her experts opined she suffers from tension headaches. Pet. Pre-hearing Memo. at 7-8; Pet. Post-hearing Memo. at 7-11. Additionally, Petitioner’s expert, Dr. Kinsbourne, opined Petitioner suffers from chronic tension headaches or NDPH. Pet. Ex. 14 at 5; Transcript (“Tr.”) 70.

Respondent’s expert neurologist, Dr. Dara Jamieson, disagrees that Petitioner has tension or tension-type headaches or NDPH, and instead, asserts that Petitioner’s presentation is consistent with cervicogenic headaches which “has no causal relationship to the [] Hep B

<sup>4</sup> Petitioner also received a tetanus, diphtheria, and pertussis (“Tdap”) vaccination on April 6, 2016. Petition at 1 (ECF No. 1); Petitioner’s Exhibit (“Pet. Ex.”) 1 at 1. Petitioner is not asserting any claim for injury related to that vaccination. Petition at ¶ 9; see generally, e.g., Pet. Pre-hearing Memorandum (“Memo.”), filed Aug. 29, 2023 (ECF No. 99).

<sup>5</sup> While the undersigned has reviewed all the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec’y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) (“We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.”); see also Paterek v. Sec’y of Health & Hum. Servs., 527 F. App’x 875, 884 (Fed. Cir. 2013) (“Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.”).

<sup>6</sup> In pre-hearing submissions and at the entitlement hearing, Petitioner alleged her injury was “tension headaches” and/or NDPH based on the opinions of her experts, Dr. Marko Bodor and Dr. Marcel Kinsbourne. See Pet. Pre-hearing Memo. at 7-8; Pet. Post-hearing Memo., filed May 17, 2024, at 7-11 (ECF No. 131). Therefore, the undersigned’s Decision addresses the alleged injury of tension or tension-type headaches and/or NDPH, and not the injury pled in the Petition (“neck pain and loss of range of motion”).

vaccinations.” Resp. Post-hearing Submission, filed Aug. 7, 2024, at 10 (ECF No. 136); see also Resp. Pre-hearing Submission, filed Sept. 29, 2023, at 11 (ECF No. 112).

The parties also dispute causation, specifically whether Hep B vaccinations can cause the alleged injury, or did so here, and if so, whether onset occurred within a medically acceptable timeframe. See Pet. Pre-hearing Memo. at 8-13; Resp. Pre-hearing Submission at 9-12.

## II. BACKGROUND

### A. Procedural History

Petitioner filed her petition on September 7, 2018, followed by medical records.<sup>7</sup> Petition; Pet. Exs. 1-13. On December 31, 2019, Petitioner filed an expert report from Dr. Kinsbourne. Pet. Ex. 14. Respondent filed an expert report from Dr. Jamieson on March 2, 2020. Resp. Ex. A. Respondent filed an amended Rule 4(c) report, arguing against compensation, on April 10, 2020. Resp. Supp. Rept. at 2.

The undersigned held a Rule 5 conference on April 23, 2020, on request of the parties. Order dated Apr. 23, 2020 (ECF No. 37). Thereafter, Petitioner filed an expert report from Dr. Bodor on August 6, 2021, and Respondent filed a supplemental expert report from Dr. Jamieson on September 24, 2021. Pet. Ex. 31; Resp. Ex. C.

Pursuant to the parties’ request, the undersigned held a second Rule 5 conference<sup>8</sup> on November 23, 2021. Rule 5 Order dated Nov. 24, 2021 (ECF No. 77) (“2021 Rule 5 Order”). The undersigned was able to provide some preliminary opinions but noted an entitlement hearing would be helpful. Id. at 2-5. An entitlement hearing was set for October 2023. Prehearing Order dated Apr. 7, 2022 (ECF No. 85). Prior to the hearing, Petitioner filed a supplemental expert report from Dr. Kinsbourne and Respondent filed supplemental expert reports from Dr. Jamieson and an expert report from Dr. You-Wen He. Pet. Ex. 33; Resp. Exs. D-E, G.

An entitlement hearing was held on October 24, 2023. Tr. 1. Dr. Bodor, Dr. Kinsbourne, Dr. He, and Dr. Jamieson testified. Tr. 3. Following the hearing, Respondent filed supplemental expert reports from Dr. Jamieson and Dr. He. Resp. Exs. J-K. The parties also filed post-hearing briefs from May 2024 to August 2024. Pet. Post-hearing Memo.; Resp. Post-hearing Submission; Pet. Reply to Resp. Post-hearing Submission (“Pet. Post-hearing Reply Memo.”), filed Aug. 15, 2024 (ECF No. 137).

This matter is now ripe for adjudication.

<sup>7</sup> Medical records were filed throughout litigation.

<sup>8</sup> Vaccine Rule 5(a) contemplates that a special master will hold a status conference to “review the materials submitted[,] [] evaluate the parties’ respective positions,” and “present tentative findings and conclusions” to facilitate the outlining of necessary proceedings for resolving the issues presented in the case. Any findings issued by the undersigned in a Rule 5 Order are only preliminary in nature.

## B. Factual History

### 1. Summary of Medical Records Prior to and After Vaccination<sup>9</sup>

Petitioner was 43 years old at the time of her subject vaccinations. Pet. Ex. 2 at 2. She had a history of tobacco use, cholecystectomy, tubal ligation, ovarian cysts, bilateral shoulder cyst excision, left shoulder pain, left shoulder bicipital tendonitis, shoulder pain with radiculopathy, and tendonitis. Id. at 3; Pet. Ex. 9 at 74-82, 95-98; Pet. Ex. 10 at 1. She had prior emergency department (“ED”) and/or hospital admissions for a breast lump, pyelonephritis, abnormal EKG, sinusitis, bronchitis, burning sores on her feet, toe pain, tendonitis, left shoulder pain and shoulder injection, and left bicipital tendonitis. See generally Pet. Ex. 9. She also had a cardiac stress test in April 2014, for tachycardia, which was normal. Pet. Ex. 10 at 17. Petitioner’s records also show that she had a car accident “years ago.”<sup>10</sup> Id. at 1.

On April 6, 2016, Petitioner presented to the Carroll County Memorial Hospital (“Carroll County”) Occupational Medicine Department (“Occupational Medicine”) for evaluation of “possible [Blood Borne Pathogen] exposure” at work. Pet. Ex. 2 at 1. Petitioner reported she worked as a housekeeper at Belterra and was cleaning trash from a room when she was pricked with a needle on her right index finger.<sup>11</sup> Id. at 2. In connection with the visit, Petitioner received a Tdap vaccination and a Hep B vaccination. Id. Petitioner was instructed to return to the medical center for a second Hep B vaccination in four weeks. Id. at 1-2.

The next day, April 7, 2016, Petitioner returned to Carroll County Occupational Medicine and was assessed with muscle tension bilaterally in neck and shoulders and “possible immunization reaction.” Pet. Ex. 2 at 9-10. Physical examination revealed mild tenseness in the cervical paraspinal, upper trapezius, and scalene muscles.<sup>12</sup> Id. at 10. She was instructed to take over-the-counter pain medication and to apply heat or ice to her neck and shoulders. Id. at 9-10.

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<sup>9</sup> Portions of this summary were taken from Respondent’s Prehearing Submission as the undersigned finds that it accurately recounts Petitioner’s medical records. Resp. Prehearing Submission at 3-7. The undersigned made edits and added additional relevant information. The undersigned has reviewed all of Petitioner’s medical records but for the sake of brevity only summarizes those most relevant to the issues herein.

<sup>10</sup> The timing of this car accident is not known.

<sup>11</sup> Petitioner sought workers’ compensation benefits associated with this incident, which were denied. See Pet. Ex. 24.

<sup>12</sup> Cervical paraspinal, upper trapezius, and scalene muscles are muscles of the neck/cervical region. See Muscle, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=32530> (last visited Apr. 22, 2025); Musculi Colli, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=90656> (last visited Apr. 22, 2025).

She was allowed to return to work with no restrictions. Id. at 9. Petitioner did not complain of a headache. See id. at 9-10.

On April 15, 2016, Petitioner presented to Carroll County ED for ongoing nausea and an episode of emesis the night before. Pet. Ex. 9 at 142. Petitioner reported she was administered vaccinations after a needle stick a few days before and wondered if her symptoms were related to the vaccinations. Id. Neurological examination was normal. Id. at 144. The ED physician diagnosed her with vomiting and discharged her home. Id. at 144-45. The records do not state that Petitioner complained of headache. See id. at 142-45.

On May 18, 2016, Petitioner returned to Carroll County Occupational Medicine for her second Hep B vaccination. Pet. Ex. 2 at 6-7. Petitioner complained of “persistent, residual [cervical spine] stiffness, much less by comparison to previous” and her end ranges of motion were “stiff.” Id. at 11. Petitioner was referred to her primary care provider (“PCP”) for further evaluation.<sup>13</sup> Id. Dr. Sherrell Nunnelley was consulted regarding Petitioner’s persistent cervical stiffness and recommended physical therapy (“PT”). Id. Petitioner did not complain of a headache. See id.

The next day, May 19, 2016, Petitioner returned to Carroll County Occupational Medicine, complaining of muscle spasms and a low-grade temperature. Pet. Ex. 2 at 12-13. Physical examination revealed “taut [cervical spine] musculature.” Id. at 13. She was diagnosed with “vaccine adverse reaction” and prescribed Flexeril and Ibuprofen. Id. at 12-13. She was not allowed to return to work due to “rigors/muscle spasm.” Id. at 12. Petitioner’s third Hep B vaccination was cancelled. Id. at 13. Treatment with rest and muscle relaxers, moist heat, ice, and gentle stretching was recommended. Id. at 12-13. The records do not document any complaint of headache. See id.

On May 23, 2016, Petitioner returned to Carroll County Occupational Medicine for follow up. Pet. Ex. 2 at 14-15. Petitioner reported she felt better, but still had a stiff neck. Id. at 15. There were no radicular symptoms. Id. Petitioner’s medical record documented a diagnosis of adverse reaction to Hep B vaccine and that she was “Allergic: Hep B.” Id. at 14-15. She was instructed to continue Flexeril and initiate Robaxin. Id. at 15. There was no documented complaint of headache. See id. at 14-15.

On May 24, 2016, Petitioner began PT at Carroll County for a stiff neck. Pet. Ex. 4 at 1; Pet. Ex. 11 at 1. At her initial evaluation, she complained that her neck was stiff, “present[ing] holding her neck stiff,” and she complained of pain from the “base of her head down into her shoulders.” Pet. Ex. 4 at 1. Physical Therapist Micheal M. Hebbeler documented “Back pain – Cervical – Lower Segment Syndrome” with pain level of 6/10 at rest and 10/10 with activity. Id. The pain was described as dull and localized. Id. “[Petitioner] report[ed] [a] headache in [the] back of head sitting up [] and lying down there [was] a headache in the frontal aspect.” Id. She

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<sup>13</sup> Petitioner was also referred to her PCP for “persistent microhematuria” due to large amount of blood in her urine. Pet. Ex. 2 at 11. She received follow up for this finding in May 2016, when she saw urologist Dr. Ranjhan K. Gopang who ordered an ultrasound that showed a possible stone in her left kidney. Pet. Ex. 3 at 5.

further reported “moderate headaches which come frequently.” Id. at 2. She was able to work, driving caused moderate pain in her neck, and her sleep was “greatly disturbed.” Id. Cervical spine range of motion was reduced. Id. at 1, 4. Impairment observation included “[l]imited mobility neck with pain and headaches and tremor-like movement.”<sup>14</sup> Id. at 2, 5. Primary diagnosis was cervicalgia (neck pain). Id. at 1. Petitioner reported therapy that day helped her headache. Id. at 6.

Petitioner’s next PT visit was May 26, 2016. Pet. Ex. 4 at 7. She was treated with hot pack, functional therapy (neck rotation and scapular retraction), followed by manual therapy relaxation and other techniques. Id. Her neck pain decreased from 8/10 to 2/10. Id. There was no mention of headache. See id. Petitioner returned for PT on May 27, May 31, June 1, June 3, June 6, June 9, and June 10. Id. at 8-15. Diagnosis remained cervicalgia. Id. On June 6, Petitioner reported relief from “forehead pressure” during certain treatment. Id. at 12. On June 9 and 10, Petitioner reported “[n]o headache today.” Id. at 13-14. Petitioner was discharged from PT to a home exercise plan on June 10. Id. at 15-17. On that date, Petitioner did not have a headache and she continued to experience limited mobility in her neck with pain. Id. at 16. Her diagnosis remained cervicalgia. Id. at 15. She was referred to a specialist. Id.

On May 27, 2016, Petitioner presented to urologist Dr. Gopang at Carrollton Internal Medicine for microscopic hematuria. Pet. Ex. 3 at 1-3. In connection with the visit, Petitioner reported neck pain and a history of “[right] shoulder surgery.” Id. at 3. Review of neurological symptoms did not note headaches. Id. Musculoskeletal review noted neck pain. Id.

Petitioner returned to Carroll County Occupational Medicine on June 6, 2016, for “[follow up] reaction to Hep B vaccine.” Pet. Ex. 2 at 16-17. Petitioner reported that her neck pain had not resolved, and she still experienced a “minor case of the shakes.” Id. at 17. Petitioner reported her pain was 3/10 at rest and 8/10 when she was trying to sleep. Id. Petitioner’s assessment was adverse reaction to vaccine and stiff neck. Id. at 16-17. Petitioner was referred to an allergist and psychiatrist. Id. Petitioner did not complain of headaches. See id.

On June 29, 2016, Petitioner returned to Dr. Gopang for follow up of her renal ultrasound, and he again recommended consultation with a urology specialist. Pet. Ex. 3 at 7-9. Petitioner also complained of neck pain and Dr. Gopang noted that Petitioner was “seeing occupational therapy.” Id. at 7. There is no mention of headache. See id. at 7-9.

On July 6, 2016, Petitioner sought treatment for her neck pain with Dr. Lester Duplechan, a physical medicine and rehabilitation physician. Pet. Ex. 2 at 18-22; Pet. Ex. 5 at 1-7; Pet. Ex. 22 at 1-4. Petitioner reported that she suffered “severe neck pain” starting on April 4, 2016.<sup>15</sup> Pet. Ex. 22 at 3. “She state[d] that she developed a toxic reaction to [Hep] B shots, causing stiffness in her neck and shaking.” Id. Petitioner denied a previous neck injury, work related neck injury, or motor vehicle wreck in the last decade. Id. Petitioner’s “pain drawing [was] over

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<sup>14</sup> Tremor or tremor-like movement is noted in several of Petitioner’s medical records. Petitioner has not alleged that her tremor was caused by vaccination.

<sup>15</sup> This date is likely an error since the date of vaccination was April 6, 2016.

the posterior neck only.” Id. Review of systems was negative for neurological conditions. Id. Physical examination revealed that Petitioner had “marked cervical protrusion posture” with reduced range of motion and abnormal musculature findings but normal upper extremity strength (5/5) and sensation. Id. Diagnosis was “[c]ervical myofascial pain, with cervical protrusion posture.” Id. at 3-4. PT was recommended. Id. at 4. There was no reference to headache in the records of this visit. See id. at 1-4.

Petitioner followed up with Dr. Duplechan on October 12, 2016. Pet. Ex. 5 at 8-19; Pet. Ex. 22 at 14-19.<sup>16</sup> She continued to have posterior neck pain without radiation but she had not attended PT due to lack of transportation. Pet. Ex. 22 at 16. She had also not had an X-ray because she did not remember the order. Id. Dr. Duplechan re-recommended PT and cervical X-rays. Id. Petitioner’s cervical X-rays showed “[r]eversal [of] the normal cervical curvature which may be secondary to spasm or positioning.” Pet. Ex. 5 at 17. There was no mention of headache at this visit. See id. at 8-19; Pet. Ex. 22 at 14-19.

Petitioner’s PT evaluation was on October 25, 2016. Pet. Ex. 24 at 7. The PT Plan of Care stated Petitioner had severe neck pain, she could hardly read due to “severe pain in [her] neck,” she had “headaches almost all the time,” she could “do most of her work, but no more,” and she could “hardly drive because of severe pain in [her] neck.” Id. at 9. Spinal assessment noted “[s]pinal stiffness especially upper cervical with chronic headaches.” Id. at 8. Petitioner returned for PT visits on October 27, 28, and 31, and Petitioner’s primary diagnosis was noted as cervicalgia. Id. at 2-4. Petitioner received traction and other treatment for her cervical spine. Id. There is no mention of headaches at those visits. See id. On November 28, 2016, Petitioner was discharged from PT as she “react[ed] to therapeutic ex[ercises] with uncontrollable ‘shaking.’” Pet. Ex. 9 at 200.

Moving forward to 2017, Petitioner followed up with Dr. Gopang on February 14, 2017. Pet. Ex. 3 at 13-15. Petitioner complained of recurring back/neck pain. Id. at 14. Dr. Gopang noted that Petitioner was allergic to the Hep B vaccine. Id. at 13-14. Review of systems noted “No Chronic Headaches” and neurological review of systems stated, “No Frequent Headaches.” Id. However, a comment was added to indicate “pain in neck and headache.” Id. at 14. Physical examination noted that Petitioner’s neck was “supple.” Id. No muscle spasms or tremors were noted. See id. Dr. Gopang diagnosed Petitioner with chronic neck pain and indicated that she was “seeing PMD from work[ers’] comp[ensation].” Id. at 15.

On February 28, 2017, Petitioner underwent a cervical spine magnetic resonance imaging (“MRI”) without contrast ordered by Dr. Gopang, for indications of “chronic worsening neck pain and stiffness with posterior headaches following her [second] [Hep B] shot.” Pet. Ex. 3 at 16. The study showed no acute findings but it revealed “[m]ultilevel cervical disc degeneration [] greatest at the C5-C6 level which produces chronic appearing mild canal stenosis and moderate bilateral foraminal stenosis.” Id. at 17. Petitioner also underwent a brain MRI on the same date that was negative. Id. at 18.

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<sup>16</sup> See also Pet. Ex. 8. Of note, this exhibit includes a cover letter from Petitioner to her attorney accompanying six pages of medical records “on my neck” sent via fax on October 19, 2016. Id. at 3.

## 2. Motor Vehicle Accident July 31, 2018

Petitioner was in a motor vehicle accident on July 31, 2018. Pet. Ex. 26 at 3. Her car was hit on the driver's side, she was restrained, and she was able to self-extricate and walk afterward, but Petitioner sustained mild to moderate left-sided hip, shoulder, and chest pain. Id. She presented to St. Elizabeth Healthcare ED the following day, August 1, 2018, where she reported a past medical history of headache and tremor. Id. at 3-4. Physical examination showed that her neck was "supple" with "[n]ormal range of motion." Id. at 4. Although Petitioner reported a history of headaches, she did not report having a headache at the visit. See id. at 3-5. X-rays of the chest, left shoulder, and left hip did not reveal any acute abnormalities. Id. at 5, 7-8.

On August 23, 2018, Petitioner was seen by orthopedist Dr. Barbara Newell for continued complaints of "pain in the center and lower part of her back" since her motor vehicle accident that had worsened since in spite of treatment with Naproxen and Medrol dose Pak. Pet. Ex. 27 at 14. Past medical history included a history "bulging disc at C5-6" and "cervical disc disorder;" headaches were not documented. Id. at 15. Review of systems was negative for headaches, neck pain, neck stiffness, or neck swelling. Id. at 17. Petitioner's gait was normal, with occasional head tremor. Id. Petitioner was to undergo further radiology studies and was referred to an orthopedic surgeon. Id.

Petitioner saw Dr. Howard Schertzinger at OrthoCincy on September 6, 2018 for injuries sustained in her recent motor vehicle accident. Pet. Ex. 28 at 3-4. She reported being in a motor vehicle accident when she was younger but denied any prior back injury. Id. at 3. She had ongoing pain 8-10/10 in the lumbar, left sacroiliac, and radiating into the left buttocks as well as left leg numbness that was worsening and affecting her activities of daily living. Id. Review of systems denied headache and was positive for cervical stiffness, lumbar, and left leg pain as well as left hand and foot numbness and a tremor. Id. Physical examination of the cervical spine noted "no deformity or swelling, left trapezius tightness, negative for pain on palpation, normal tone of arms, [and] symmetric full range of motion." Id. at 4. Diagnosis was cervical and lumbar sprain, myofascial pain (traumatic), motor vehicle accident, moderate L5/S1 degenerative disc disease that was pre-existing with substantial aggravation. Id. Dr. Schertzinger noted Petitioner had "[o]ngoing cervical and lumbar pain since [motor vehicle accident]." Id. MRI of the lumbar spine performed September 17, 2018 showed "[s]hallow central to left paracentral disc protrusion which mildly effaces the thecal sac, touching the descending left S1 nerve root . . . without nerve root displacement. No foraminal narrowing." Pet. Ex. 29 at 39.

On September 21, 2018, Petitioner returned to Dr. Schertzinger for treatment of lumbar injuries she sustained in the motor vehicle accident. Pet. Ex. 27 at 12. At this visit, physical examination did not reveal any neurological abnormalities or abnormalities of her cervical spine or neck.<sup>17</sup> Id. Headaches were not mentioned. Id. Cervical spine X-rays were recommended, but Petitioner "denied" the request. Id. at 13. Plan was for PT. Id.

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<sup>17</sup> "[P]araspinal muscle tightness" was documented in the context of her lumbar injury. Pet. Ex. 27 at 12.

Petitioner presented for PT on October 1, 2018. Pet. Ex. 28 at 29-33. There was no evaluation of her cervical spine and no complaints of headache. Id.

She returned to see Dr. Schertzinger on October 19, 2018, following five PT sessions, complaining that traction was “awful” and caused more pain, but therapy and home exercises had helped. Pet. Ex. 27 at 9-10. There were no documented complaints of neck pain or headache. See id.

She saw Dr. Schertzinger on November 15, 2018 for “treatment of her ongoing back pain.” Pet. Ex. 28 at 9-10. She did not complain of headaches. See id. at 9. A surgical consult with Dr. John B. Jacquemin was recommended for her back pain. Id. at 10.

On December 21, 2018, Petitioner saw Dr. John B. Jacquemin. Pet. Ex. 27 at 6-7. Petitioner did not complain of a headache. See id. Diagnosis was lumbago and left lower extremity radiculopathy. Id. at 7. Surgical intervention was not indicated. Id. Petitioner was referred to another physician, Dr. Robert Klickovich. Id.

Petitioner saw Dr. Klickovich at Paradigm Pain and Spine Consultants on August 2, 2019. Pet. Ex. 29 at 10. In the new patient questionnaire, she reported lower back, buttock, and left leg pain. Id. at 2. Petitioner did not report cervical pain or headaches. See id. at 1-9. Under allergies, she listed the Hep B vaccine, noting her adverse reaction as “tremors [and] stiff neck.” Id. at 9. In review of systems, Petitioner denied neck pain and headaches. Id. at 10-11. Physical examination revealed her neck was supple with full range of motion. Id. at 10. Neurologic examination noted no tremor, and normal tone and reflexes. Id. at 11. Of note, Petitioner “claim[ed] that she had no issues prior to the [motor vehicle accident].” Id. at 11.

Petitioner returned to see Dr. Jacquemin on January 24, 2020, reporting continued low back pain with radiation into the leg despite treatment by Dr. Klickovich, which included injections, radiofrequency ablations, and epidural injections without relief. Pet. Ex. 28 at 16. Headache was not mentioned. See id. at 16-17.

Registered Nurse Practitioner Ana Carolina Baptista-Wise saw Petitioner on February 7, 2020. Pet. Ex. 28 at 18-19. There was no mention of headache. See id. When Petitioner saw Dr. Jacquemin next on March 13, 2020, there had been no changes since her prior visit. Id. at 20-21. Headaches were not reported. See id.

### **3. Records Related to Headache in 2020**

Petitioner had a New Patient Evaluation with Dr. Duplechan on May 19, 2020. Pet. Ex. 25 at 3-4. Dr. Duplechan’s history taken from Petitioner stated that he had seen her four years

before for “headaches.”<sup>18</sup> Id. at 4. Petitioner reported that she had headaches in the occipital area, two to three times a week. Id. Petitioner also informed Dr. Duplechan that she had a vaccine injury case and that her vaccine was “thought to be the cause of the headache.” Id. Petitioner described her headaches as “heavy” with “fluid build up over back of head, with radiation over the vertex<sup>[19]</sup> of the head.” Id. Physical examination showed “marked cervical protrusion posture” with shoulders forward and protraction of the scapulae. Id. Her muscles were tight in the trapezius and cervical paraspinals. Id. at 4-5. She also had abnormalities of the lumbar spine. Id. at 5. Diagnoses were “[c]ervical myofascial pain, with cervical protrusion posture” and “[l]umbar degenerative disk disease, with reduced segmental motion and poor posture.” Id. PT was recommended. Id.

Petitioner had a telephone call encounter with Dr. Reena Shah at UC Heath Service on September 30, 2020 for headaches. Pet. Ex. 30 at 2-15. Allergy to the Hep B vaccine was noted, with reaction as headache, tremor, stiff neck, shakes, and anaphylaxis. Id. at 2. Medications included ibuprofen 800 mg as needed. Id. at 4. Petitioner reported that her headaches began in 2016, when she had an allergic reaction to the Hep B vaccination. Id. She had a “stiff neck, headaches, [and] tremors.” Id. She complained that “[h]er headaches have remained the same through the years.” Id. They occurred more than three times per week and were located in the back and frontal areas of her head. Id. The pain radiated to her neck, and was described as dull, pulsating, and achy. Id. Her level of pain was currently 1/10 and could be as great as 8-9/10. Id. Her associated symptoms included “dizziness, loss of balance, nausea, sensitivity to sound, ringing in the ears,” and high pitched tinnitus. Id. She also experienced sensitivity to light. Id. at 4-5. Her symptoms were improved by lying down and Tylenol. Id. at 5. Gabapentin, taken for her back, made her headaches worse. Id. Petitioner reported that she had seen Dr. Duplechan for “chronic cervical myofascial pain” but treatment for that condition did not improve her headaches. Id. Physical examination and neurological examination were normal. Id. at 6-7. Motor strength was normal in all muscle groups of the upper and lower extremities and reflexes were normal. Id. at 7. She had no tremor. Id. at 7-8. Diagnosis was chronic migraine. Id. at 8. Treatment with medications was planned. Id.

Dr. Shah’s next visit with Petitioner was held via telehealth video on November 24, 2020, to follow-up with Petitioner’s migraine headaches. Pet. Ex. 30 at 16-26. Petitioner was taking Nortriptyline, but it made her “moody.” Id. at 19. Additionally, the medication decreased the severity of her headaches but not the frequency. Id. Sumatriptan improved but did not completely relieve the pain, and Compazine helped the nausea. Id. Dr. Shah changed Petitioner’s Nortriptyline to Impramine. Id. at 20.

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<sup>18</sup> Although Dr. Duplechan stated he previously saw Petitioner for headaches, his records show he treated Petitioner for neck pain. On July 6, 2016, Petitioner sought treatment with Dr. Duplechan for her neck pain. Pet. Ex. 2 at 18-22; Pet. Ex. 5 at 1-7; Pet. Ex. 22 at 1-4. Petitioner returned to Dr. Duplechan on October 12, 2016 for follow up of her neck pain. Pet. Ex. 5 at 8-19; Pet. Ex. 22 at 14-19.

<sup>19</sup> Vertex refers to “the top or crown of the head.” Vertex, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=52962> (last visited Apr. 22, 2025).

No additional records were filed.

#### **4. Petitioner's Affidavit**

Petitioner executed an affidavit on December 6, 2019. Pet. Ex. 13 at 2. She averred that the day after receiving the Hep B and Tdap vaccinations on April 6, 2016, she “had a stiff neck with tremors and a headache.” Id. at ¶¶ 3-4. She further stated that she continued to have “these symptoms ever since.” Id. at ¶ 4. When she received the second Hep B vaccination on May 18, 2016, her tremors and headache worsened. Id. at ¶ 5. Petitioner stated that because of her second reaction, her doctor cancelled the third Hep B vaccine in the series. Id.

Regarding the headaches that began on April 7, 2016, Petitioner stated the headache was “constant” for “around eight months” after which it became intermittent. Pet. Ex. 13 at ¶ 6. As of the date she signed her affidavit in 2019, Petitioner averred her headache occurred three to four days per week. Id. While the intensity of her headaches varied, “the type of headache [was] always the same.” Id. at ¶ 7. “[Her] headache is in the back of [her] head and feels like pressure.” Id. While it causes pain, “it is not so bad that [she] can’t function.” Id. Petitioner sometimes has nausea with her headaches. Id.

#### **C. Expert Reports**

##### **1. Petitioner's Expert, Dr. Marcel Kinsbourne<sup>20</sup>**

###### **a. Background and Qualifications**

In 1955, Dr. Kinsbourne obtained his B.M., B.Ch. from Oxford University Medical School, and he completed postdoctoral training through 1964 in the United Kingdom. Pet. Ex. 38 at 1. Thereafter, he obtained board certification in neurology and licensing in the United States and Canada and worked as a professor at various teaching institutions. Id. at 2-3. Dr. Kinsbourne served on several editorial boards and authored or co-authored more than 400 publications. Id. at 4-38.

At the time of hearing, he testified that he had not practiced pediatric neurology since the 1990s. Tr. 68. During his practice, he did not focus on headache disorders. Tr. 69-70.

###### **b. Diagnosis Opinion**

In his initial expert report, Dr. Kinsbourne opined that Petitioner had tension headaches and/or NDPH. Pet. Ex. 14 at 3. He explained that tension headaches are characterized by pressure or tightness (but not pulsating), bilateral in location, of moderate intensity, relating to the back of head and neck, are associated with muscular stiffness in the neck, occipital, and

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<sup>20</sup> Dr. Kinsbourne submitted two expert reports and testified at the hearing. Pet. Exs. 14, 33; Tr. 3. Dr. Kinsbourne was a long-time and well-respected expert in the Vaccine Program. He passed away in April 2024.

frontal areas, and myofascial symptoms in the neck and shoulders.<sup>21</sup> Id. In chronic tension headaches, the “pain arises at the back of the neck” and “radiates to the occipital scalp and streams to bifrontal scalp.” Pet. Ex. 33 at 2.

The second diagnosis offered by Dr. Kinsbourne was NDPH. Pet. Ex. 14 at 3. NDPHs are “primary daily headaches unremitting from onset.” Pet. Ex. 17 at 1.<sup>22</sup> This type of headache is rare. Pet. Ex. 21 at 1.<sup>23</sup> Associated events may include infection, influenza (“flu”)-like illness, stress, surgical procedures, ingestion of or withdrawal of certain medications, human papillomavirus (“HPV”) vaccination, hormone therapy, toxin exposure, cervical massage, syncope, and thyroid conditions, although a precipitating event may not be present. Id. at 3. There are also conditions that mimic NDPH, such as elevated cerebrospinal fluid pressure, headaches caused by trauma, and meningitis.<sup>24</sup> Id. at 5, 5 tbl.4.

The International Classification of Headache Disorders provides diagnostic criteria for NDPH:

- A. Headache for more than [three] months fulfilling criteria B-D
- B. Headache is daily and unremitting from onset or less than [three] days from onset
- C. At least [two] of the following pain characteristics:
  - 1. Bilateral location
  - 2. Pressing/tightening (nonpulsating) quality
  - 3. Mild or moderate intensity
  - 4. Not aggravated by routine physical activity such as walking or climbing stairs
- D. Both of the following:
  - 1. No more than one of photophobia, phonophobia, or mild nausea
  - 2. Neither moderate or severe nausea or vomiting
- E. Not attributed to another disorder

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<sup>21</sup> Dr. Kinsbourne mentioned two articles in support of the diagnosis of tension headaches. However, Petitioner did not file these articles.

<sup>22</sup> M.S. Robbins et al., Clinical and Prognostic Subforms of New Daily-Persistent Headache, 74 Neurology 1358 (2010).

<sup>23</sup> Nooshin Yamani & Jes Olesen, New Daily Persistent Headache: A Systematic Review on an Enigmatic Disorder, 20 J. Headache & Pain 1 (2019).

<sup>24</sup> Meningitis is “inflammation of the meninges, usually by either a bacterium . . . or a virus.” Meningitis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=30340> (last visited Apr. 22, 2025). Meninges refers to “the three membranes that envelop the brain and spinal cord: the dura mater, arachnoid, and pia mater.” Meninges, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=30334> (last visited Apr. 22, 2025).

Pet. Ex. 17 at 2 tbl.1.

According to Dr. Kinsbourne, Petitioner satisfied criteria A and B because her headache lasted longer than three months and was unremitting for eight months. Pet. Ex. 14 at 3. He further opined she met criterion C because she had a bilateral location and pressure/tightening without a pulsating quality to her headaches. Id. For criterion D, he noted Petitioner did not complain of light sensitivity or photophobia and had only one episode of vomiting. Id. at 4. Lastly, Petitioner had no evidence of any other headache disorder under criterion E. Id.

In support of his opinion that Petitioner had NDPH, he cited a paper by Yamani and Olesen. Pet. Ex. 21. These authors describe NDPH as a “rare[,] primary headache disorder, characterized by persistent headache” that begins “with a clearly remembered onset and continues in a daily pattern without remitting.” Id. at 1. These headaches are “often disabling” and may “significantly affect . . . quality of life.” Id.

Dr. Kinsbourne noted that Petitioner’s pain involved her neck and shoulder muscles and was aggravated by neck movements. Pet. Ex. 14 at 4. He added that Petitioner’s headaches affected her ability to concentrate and made it hard to sleep. Id.

While his first expert report suggested tension headaches and NDPH were two different entities, at the hearing Dr. Kinsbourne testified that they were the same thing. Tr. 71. In his second expert report, Dr. Kinsbourne wrote, “NDPH is a chronic tension headache syndrome. The pain and stiffness are muscular. The pain arises at the back of the neck, the muscles . . . are tender, and [the pain] radiates to the occipital scalp and streams to bifrontal scalp.” Pet. Ex. 33 at 2. He testified that the fact that Petitioner was noted to have cervical protrusion posture, a curved concave back due to tense muscles supported the diagnosis and weighed against a diagnosis of migraine headaches. Tr. 63.

Dr. Kinsbourne disagreed that Petitioner had chronic migraine headaches, asserting “her condition is nothing like migraine.” Tr. 75-76. He based this opinion on the lack of an aura<sup>25</sup> at the onset of her headaches and the lack of involvement of the cerebral cortex.<sup>26</sup> Tr. 76. Migraines are “neurological” whereas tension headaches are “musculoskeletal.” Pet. Ex. 33 at 1. Further, migraines have phases, including a prodrome (lasting several hours to days), aura

<sup>25</sup> An aura is “a subjective sensation or motor phenomenon that precedes and marks the onset of an episode of a neurologic condition, particularly an epileptic seizure . . . or a migraine.” Aura, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=4862> (last visited Apr. 22, 2025).

<sup>26</sup> The cerebral cortex is “the thin (about 3 mm) layer or mantle of gray substance covering the surface of each cerebral hemisphere . . . responsible for the higher mental functions, for visceral functions, for motor and sensory functions, for perception and behavioral reactions, and for the association and integration of these function.” Cerebral Cortex, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=67193> (last visited Apr. 22, 2025).

(lasting up to one hour, although not always present), headache (lasting four to 72 hours, and usually unilateral), and postdromal phase (lasting one to two days).<sup>27</sup> Id. at 1.

In his second report, responsive to the opinions of Respondent's expert neurologist, Dr. Jamieson, Dr. Kinsbourne again opined that Petitioner did not have migraine headaches. Pet. Ex. 33 at 1. In support of this opinion, he referenced a text about migraines from the Cleveland Clinic.<sup>28</sup> Pet. Ex. 34. Common triggers included emotional stress, not eating, chemical or food sensitivity, caffeine, hormonal changes in women, flashing lights, fatigue, changes in sleep patterns, and others. Id. at 10-12. Vaccines were not listed as triggers for migraines. See id.

### c. Causation Opinion

#### i. Althen Prong One

Dr. Kinsbourne conceded that “[t]he mechanism of the underlying pathology in NDPH is unknown.” Pet. Ex. 14 at 4. The fact that the headache is relentless and intractable “affords little help in inferring a causal mechanism.” Id. While the mechanism is not known, Dr. Kinsbourne noted that this type of headache is “abruptly triggered” and he opined that viral infections frequently act as triggers. Id. He conceded there is no study showing that infection invades the brain to cause this type of headache. Id. Dr. Kinsbourne suggested that an infection “interacts” with an “unidentified susceptibility . . . to elicit a low-level immune reaction, perhaps neuroinflammatory, that becomes chronic.” Id. He opined that vaccination is also a “potential trigger.” Id. Dr. Kinsbourne did not cite any medical literature or other evidence to support his opinion that vaccinations can trigger NDPH through his purported mechanisms.

According to Dr. Kinsbourne, “[t]he brief one-day interval between vaccination and headache onset . . . suggests [] a proinflammatory cytokine reaction was instrumental in inducing the apparent inflammatory changes around the brain.” Pet. Ex. 14 at 4. Although he noted that severe stress may also trigger NDPHs, he opined this association “does not [] imply an alternative mechanism” (to his proinflammatory cytokine reaction) since stress elevates the excitation/inhibition ratio of cytokine interleukin (“IL”)-6. Id. He cited a paper by Garcia-Oscos et al.<sup>29</sup> in support of his opinion about cytokine IL-6; however, Garcia-Oscos et al. appears to

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<sup>27</sup> For Dr. Kinsbourne's list of specific symptoms of each phase of a migraine headache, see Pet. Ex. 33 at 1-2.

<sup>28</sup> Migraine Headaches, Cleveland Clinic, <https://my.clevelandclinic.org/health/diseases/5005-migraine-headaches> (last reviewed Mar. 3, 2021).

<sup>29</sup> Francisco Garcia-Oscos et al., The Stress-Induced Cytokine Interleukin-6 Decreases the Inhibition/Excitation Ratio in the Rat Temporal Cortex via Trans-Signaling, 71 Biological Psychiatry 574 (2012).

relate to the question of whether “pro-inflammatory cytokines can alter synaptic function”<sup>30</sup> in the brain. Pet. Ex. 15 at 5. And Dr. Kinsbourne did not opine synaptic function of the brain is somehow dysregulated so as to cause headaches. The article appears to relate to mechanisms which may cause conditions like epilepsy, not headaches. Thus, the article does not appear to be relevant.

Another basis for Dr. Kinsbourne’s suggested mechanism of proinflammatory cytokine induction is based on the effectiveness of methylprednisolone<sup>31</sup> in treating NDPH. Pet. Ex. 14 at 4. He cited a study from Prakash and Shah<sup>32</sup> of NDPH patients treated with methylprednisolone. Pet. Ex. 16. The authors suggested chronic meningeal inflammation as the possible theory of causation; however, the authors suggested this only as a “possibility.” Id. at 10 (“This indirectly suggests a possibility of meningeal involvement in a subset of patients with NDPH . . .”). Further, the study reported “[m]ost of [the] patients had nausea, photophobia, or phonophobia.” Id. Petitioner did not report photophobia or phonophobia in association with headache after vaccination. Pet. Ex. 14 at 4. Moreover, none of Petitioner’s physicians ever suggested she had meningeal inflammation.

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<sup>30</sup> Synaptic function “pertain[s] to or affect[s] a synapse,” which is “the site of functional apposition between neurons, at which an impulse is transmitted from one neuron to another, usually by a chemical neurotransmitter (e.g., acetylcholine, norepinephrine) released by the axon terminal of the excited (presynaptic) cell. The neurotransmitter diffuses across the synaptic cleft to bind with receptors on the postsynaptic cell membrane, and thereby effects electrical changes in the postsynaptic cell which result in depolarization (excitation) or hyperpolarization (inhibition).” Synaptic, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=48437> (last visited Apr. 22, 2025); Synapse, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=48435> (last visited Apr. 22, 2025).

<sup>31</sup> Methylprednisolone is “a synthetic glucocorticoid derived from progesterone, used in replacement therapy for adrenocortical insufficiency and as an antiinflammatory and immunosuppressant in a wide variety of disorders.” Methylprednisolone, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=31014> (last visited Apr. 22, 2025).

<sup>32</sup> Sanjay Prakash & Nilima D. Shah, Post-Infectious New Daily Persistent Headache May Respond to Intravenous Methylprednisolone, 11 J. Headache & Pain 1 (2009).

Additionally, Dr. Kinsbourne cited Rozen and Swidan,<sup>33</sup> who described elevated levels of TNF alpha, a proinflammatory cytokine, in the cerebrospinal fluid of patients with NDPH. Pet. Ex. 14 at 5 (citing Pet. Ex. 18). According to Dr. Kinsbourne, the research suggested that ongoing cytokine production after infections may cause “chronic glial inflammation.” Id. Based on this hypothesis, treatment with cytokine/glial inhibitors has been studied with promising results. Id.

Another article cited by Dr. Kinsbourne, Yamani and Olesen, reviewed medical literature related to NDPH. Pet. Ex. 21. Vaccinations in general were not identified as precipitating factors. Id. at 3. The authors noted one study that documented HPV vaccination as a precipitating factor. Id. at 3, 5 tbl.3 (citing Pet. Ex. 17 at 3). Hep B vaccinations were not identified. Id. at 3. Relative to pathogenesis, infections were identified as potential precipitating factors, but vaccinations were not mentioned. Id. at 3-5. The authors concluded that the “most proposed pathogenic mechanisms are somewhat speculative. . . . Thus, NDPH remains enigmatic and in need of further controlled studies of its mechanism.” Id. at 5.

A study by Della Vedova et al.,<sup>34</sup> examining the role of proinflammatory cytokines in tension-type headaches, cited by Dr. Kinsbourne, noted an increase in the cytokine IL-1 $\beta$  levels in patients with headaches. Pet. Ex. 20 at 4-5. However, the authors noted that the findings were limited due to the small number of patients studied. Id. Vaccinations were not discussed.

Lastly, Dr. Kinsbourne opined that infections trigger NDPH, and this process is influenced by yet to be discovered host factors. Pet. Ex. 14 at 4-5. He explained that “[i]nfections and vaccinations share surface epitopes that activate the immune system, and the immune activation that triggers NDPH arises largely from nonspecific infectious causes.” Id. He analogized that since there is evidence that HPV vaccination is a trigger of NDPH, other vaccines such as the Hep B vaccine can also trigger NDPH. Id.; see Pet. Ex. 17 at 3; Pet. Ex. 21 at 3, 5 tbl.3.

Specific to vaccine causation, Dr. Kinsbourne does not cite any medical article associating NDPH with Hep B vaccination. He does not explain how the Hep B vaccination induces cytokine production in an ongoing or persistent manner so as to cause a chronic type of headache. And while he cited one case report of headache two days after a second HPV

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<sup>33</sup> Todd Rozen & Sahar Z. Swidan, Elevation of CSF Tumor Necrosis Factor  $\alpha$  Levels in New Daily Persistent Headache and Treatment Refractory Chronic Migraine, 47 Headache 1050 (2007). Petitioner filed only the abstract of the article. For this reason, the undersigned is unable to verify Dr. Kinsbourne’s statement that “Rozen and Swidan inferred the NDPH patients have persistent cytokine production following infections that results in chronic glial inflammation.” Pet. Ex. 14 at 5. Regardless, the article does not relate to vaccinations. Dr. Kinsbourne did cite an article by Yamani and Olesen which discussed a hypothesis of “persistent glial activation” in the context of proinflammatory cytokines. See Pet. Ex. 21 at 4-5.

<sup>34</sup> Chris Della Vedova et al., Peripheral Interleukin-1 $\beta$  Levels Are Elevated in Chronic Tension-Type Headache Patients, 18 Pain Rsch. & Mgmt. 301 (2013).

vaccination, he does not explain how the Hep B vaccine is similar to the HPV vaccine so as to assume it is a causative trigger.

### ii. Althen Prong Two

Regarding prong two, Dr. Kinsbourne opined that Petitioner's NDPH was "triggered by her closely preceding [Hep] B vaccination." Pet. Ex. 14 at 5. He asserted onset was "dramatically abrupt both after the first and second [Hep B] vaccination." Id.

In addition to temporal proximity, Dr. Kinsbourne stated that Petitioner's treating physicians attributed the cause of her headaches to the Hep B vaccination. Pet. Ex. 14 at 5. However, he agreed that Petitioner's treating physicians did not diagnosis tension headaches or NDPH. Tr. 78.

Lastly, he opined that there were no alternative causes for Petitioner's headaches. Pet. Ex. 14 at 5. He disagreed that Petitioner's MRI showed age-related cervical stenosis or any significant cervical pathology that would account for her symptoms. Tr. 65, 72-73. He opined Petitioner's prior car accident, which caused shoulder pain with radiculopathy, was not relevant. Tr. 74. He testified that he did not know whether the car accident post-vaccination, in July 2018, played any role in causing or contributing to Petitioner's headaches. Tr. 84-85.

### iii. Althen Prong Three

In support of prong three, Dr. Kinsbourne opined the interval between vaccination and disease onset was medically reasonable. Pet. Ex. 14 at 5. He testified that proinflammatory cytokines caused fever and headache within one day. Tr. 79, 82.

According to Dr. Kinsbourne, Petitioner received two Hep B vaccinations and within one day of each vaccination she developed a headache. Tr. 82. Dr. Kinsbourne testified that the onset of her severe headache was one day after the first Hep B vaccination (April 6, 2016). Id. Over the next six weeks, the headache faded away completely. Id. Petitioner received the second Hep B vaccination (May 16, 2016), and her headache returned within 24 hours. Id. The headache did not go away. Id. He opined this scenario represented challenge/rechallenge. Id.

Dr. Kinsbourne was unable, however, to provide a reference in the medical record to support his opinion that Petitioner developed a headache the day after her initial Hep B vaccination on April 7, 2016. See Tr. 83-84. Regardless, he opined that Petitioner had extreme spasm that caused a headache. Id.

## 2. Petitioner's Expert, Dr. Marko Bodor<sup>35</sup>

### a. Background and Qualifications

Dr. Bodor received an A.B. in Biology from Harvard College and an M.D. from University of Cincinnati. Pet. Ex. 37 at 1. Following medical school, he completed a surgical internship at University of California, San Diego and a residency in physical medicine and rehabilitation at University of Michigan. Id. He is board certified in physical medicine and rehabilitation with subspecialties in pain medicine and sports medicine. Id. He has a private practice and holds other positions concurrently as well as two hospital affiliations. Id. Throughout his career, he has authored or co-authored approximately 50 publications. Id. at 10-12. He has specifically published on shoulder pain and injury following vaccine administration. Tr. 7. Dr. Bodor has also published a paper on cervical facet joints as a cause of chronic neck pain. Tr. 8. His curriculum vitae, however, does not identify any specialty training in the diagnosis or treatment of headaches, or list any presentations or publications related to the diagnosis or treatment of headaches. See Pet. Ex. 35.

### b. Diagnosis Opinion

In his expert report, Dr. Bodor agreed with Dr. Kinsbourne that Petitioner suffered from tension headaches. Pet. Ex. 31 at 2. He stated that “[t]he medical records clearly establish the onset of her spasms and headaches” after she received her vaccines on April 6, 2016. Id. at 2-3. He further opined that Petitioner’s tension headaches are “chronic and most likely will remain so.” Id. at 3.

At the hearing, however, Dr. Bodor offered two additional differential diagnoses. Tr. 31. He also offered a caveat, noting that he had not examined Petitioner. Id. Since he had not examined Petitioner, tension headache was “number one” on his “differential diagnosis.” Id. His second differential diagnosis was “tension-migraine” and his third was “cervicogenic headache.” Id.

Dr. Bodor could not identify the diagnostic criteria for tension headaches. Tr. 32. Instead, he based the diagnosis on his training and education in medical school and residency. Tr. 32-33. Dr. Bodor defined “tension-migraine” as an “overlap between a tension headache and a migraine headache,” with features of both. Tr. 33. Tension headaches have a “hatband distribution” of pain, whereas the pain in a migraine is usually on one side. Id. Although he testified that he based these definitions on the medical literature, Dr. Bodor was unable to reference any specific literature or a consensus statement to support his definitions. Tr. 33-34.

In support of the differential diagnosis of “tension-migraine” Dr. Bodor referenced Dr. Shah’s diagnosis of migraine in 2020. Tr. 34. Dr. Bodor opined that the diagnosis of tension-migraine was “less probable” and only a “second possibility.” Tr. 35-36.

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<sup>35</sup> Dr. Bodor submitted one expert report and testified at the hearing. Pet. Ex. 31; Tr. 3.

Dr. Bodor's third differential diagnosis was cervicogenic headache, and he ranked this diagnosis at the same level as tension-migraine. Tr. 40.

**c. Causation Opinion**

**i. Althen Prong One**

Regarding causation, Dr. Bodor offered a short explanation in his expert report, stating that “[p]ain in the deltoid muscles ( . . . caused by vaccination) can trigger spasms in the trapezius, levator scapulae[,] and other muscles of the neck.” Pet. Ex. 31 at 3.

**ii. Althen Prongs Two and Three**

At the hearing, Dr. Bodor offered two mechanisms of causation specific to Petitioner that he did not discuss in his expert report. Tr. 19-21, 42-44. His first mechanism was based on overuse of muscles leading to headaches. Tr. 19-21. He testified that Petitioner “probably [had] a predisposition to having tension migraines” and the “vaccination was [] the straw that broke the camel’s back.” Tr. 19-20. Dr. Bodor opined Petitioner had pain in the deltoid muscle, causing her “to use other muscles to abduct her shoulders.” Tr. 20. These other muscles attach to the head, the back of the head, and the neck, and function to rotate the scapulae, to “rotate the arm and abduct the shoulder.” Id. “So if the deltoid muscles were sore, then these other muscles would be overused and could trigger pain and tightness and trigger a cycle of tension headaches that could persist even after the original stimulus ha[d] resolved.” Id. He later referred to this as a “mechanical mechanism” due to an “acute change in the mechanics” of using the shoulder muscles, caused by substituting other muscles “for a deltoid muscle that might be in pain.” Tr. 43-44.

His next “possible mechanism” was based on “nonspecific inflammation” that made Petitioner’s neck stiff. Tr. 21. “The inflammation from the vaccinations could have started a cycle of muscle tightness and stiffness, [] that in the right person [] started this cycle of tension migraines.” Id. Inflammation was “a possible precipitating factor.” Tr. 42.

When asked on cross-examination which of the two mechanisms was more likely than not, Dr. Bodor opined they were “fifty-fifty” and both were “equally probably.” Tr. 45.

Dr. Bodor analogized these mechanisms to those that cause complex regional pain syndrome (“CRPS”), a condition which “creates a windup where the pain just kind of winds up and increases.” Tr. 22. The “exact reasons” why the pain is perpetuated are “not known.” Id. He agreed that Petitioner did not have CRPS. Tr. 45-46.

Dr. Bodor also summarized the relevant medical records that document muscle tension and/or stiffness in Petitioner’s neck and bilateral shoulders. Tr. 9-12. The focus of this testimony was muscle tension and seemed to reflect a mechanism based on muscle tension.

The day after her first vaccinations on April 6, 2016, Petitioner had muscle tension in her neck and bilateral shoulders. Tr. 9 (citing Pet. Ex. 2 at 9-10). On May 18, 2016, after her second

Hep B vaccination, she had “persistent stiffness.” Tr. 10 (citing Pet. Ex. 2 at 1). The next day, May 19, she had muscle spasm and low grade fevers. Tr. 11 (citing Pet. Ex. 2 at 12). A PT evaluation on May 24 noted decreased range of motion. Tr. 11-12 (citing Pet. Ex. 11 at 1-2). She continued to have limited mobility on June 10. Tr. 13 (citing Pet. Ex. 4 at 15-16). When Petitioner saw Dr. Duplechan on July 6, 2016, she had “stiffness in neck and shaking.”<sup>36</sup> Tr. 13-14 (citing Pet. Ex. 2 at 18-19). Dr. Bodor agreed that the shaking was not witnessed by Dr. Duplechan. Tr. 53. He further opined that Petitioner’s shaking did not have anything to do with her headache. Id.

MRI done on February 28, 2017 showed “[m]ild reversal of normal lordosis [] centered around [] C-5.” Tr. 15 (quoting Pet. Ex. 3 at 16-17). Dr. Bodor opined that reversal of normal cervical lordosis is associated with muscle spasm or cervical degeneration. Id. Without reviewing the MRI images (as opposed to the report), Dr. Bodor was unable to determine whether Petitioner’s reversal of normal lordosis was caused by degeneration or not. Tr. 16. He explained it is “not a very specific finding” and can be caused by many different things, including posture, disc degeneration, prior car accident, or muscle spasm. Tr. 16, 50-51.

Petitioner’s MRI also showed “small disk bulges, or osteophytes” at C-2 through C-7 representing all levels, mild stenosis on the right at C-3 to C-4 and bilaterally at C-5 to C-6, and mild right-sided facet degeneration. Tr. 15. He characterized such evidence of degenerative changes as age related and not significant. Tr. 46. Dr. Bodor did not attribute Petitioner’s headache to her cervical degenerative findings, however, he agreed Petitioner had objective cervical disk degeneration at multiple levels of her cervical spine. Id. Dr. Bodor also agreed that Petitioner’s cervical degenerative disk disease was not caused by her vaccinations. Id.

Moving forward several years, Dr. Bodor next discussed a visit by Petitioner to Dr. Duplechan in May 2020, where she reported continued headaches in the occipital location, occurring two to three times per week, and numbness down the arm. Tr. 16-17 (citing Pet. Ex. 25 at 4-5). Dr. Duplechan’s diagnoses was cervical myofascial pain and referred Petitioner to Dr. Shah for evaluation of chronic headache. Tr. 17. Dr. Bodor then discussed Dr. Shah’s note, which included Petitioner’s history, physical examination, and diagnosis. Tr. 17-18 (citing Pet. Ex. 30 at 4-8). Physical examination did not reveal “any specific focal abnormalities.” Tr. 18. Diagnosis was chronic migraine. Id.

Dr. Bodor opined that Petitioner’s Hep B vaccinations played a role in the development of her neck tension and resulting problems, although his opinion was limited because he had not “personally examined” Petitioner and based his opinion on the medical records. Tr. 24. Based on Petitioner’s medical records, she did not have “this type of problem before,” and “it started within 24 hours” of each Hep B vaccination. Id. He opined that when her problems reoccurred after receipt of the second Hep B vaccination, which was “test/retest, challenge/rechallenge,” there was evidence of an association with vaccinations and such vaccination caused her to

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<sup>36</sup> Both Dr. Kinsbourne and Dr. Bodor occasionally reference Petitioner’s shaking or tremors. However, Petitioner has not alleged any vaccine-related injury relative to this symptoms, and therefore, the undersigned does not discuss them further.

“develop[] the tightness in the neck and stiffness and headache.” Id. Additionally, Petitioner’s providers withheld the third Hep B vaccine. Tr. 25.

According to Dr. Bodor, the initial trigger for Petitioner’s tension headaches was “the vaccine and the tension.” Tr. 27. This type of headache is caused by the muscles of the head and neck (trapezius, scalenes, levator scapulae, frontalis, temporalis, and occipitalis muscles) being tight. Tr. 25. When these muscles tense up, tension headaches occur. Id. In contrast, cervicogenic headaches are caused by structures in the neck, usually the facet joints at C-2 to C-3 and the C-1 to C-2 articulation between the head and neck. Tr. 25-26. However, Dr. Bodor explained that pain at the C-2 and C-3 joints can also cause tension headaches. Tr. 26. Specific to Petitioner, the primary cause of her headaches was the muscular tension in the side and back of her neck, as well as a C-2 and C-3 component. Id. While the initial trigger of Petitioner’s headaches was tension due to the vaccines, Dr. Bodor testified that since her headaches were chronic, she may “possibly” also have a C-2 to C-3 joint component. Tr. 27. He referenced this as “overlap,” explaining that “multiple factors [] may be perpetuating pain.” Tr. 26-27.

As for prong three, he opined an onset within of 24 hours was “definitely” appropriate to implicate the vaccines. Tr. 24.

### **3. Respondent’s Expert, Dr. Dara G. Jamieson<sup>37</sup>**

#### **a. Background and Qualifications**

Dr. Jamieson is a board-certified neurologist. Resp. Ex. A at 1; Resp. Ex. I at 2. She received her medical degree from the University of Pennsylvania, followed by a neurology residency and a cerebrovascular fellowship at the University of Pennsylvania Hospital. Resp. Ex. I at 1. Dr. Jamieson was a practicing neurologist for 32 years before transitioning to a faculty appointment. Resp. Ex. A at 1. She is currently a Clinical Associate Professor of Neurology at Weill Cornell Medicine, where she teaches medical students, residents, and fellows. Id. Dr. Jamieson has lectured extensively on multiple neurological topics. Id. She serves as an editor and reviewer for several neurology journals. Id. Dr. Jaimeson has authored or co-authored numerous neurology papers, chapters, and review articles as well as authored two books. Id. at 1; Resp. Ex. I at 10-15. She has been a member of the American Headache Society since 2000 and has a specialty board certification in Headache Medicine from United Council for Neurological Subspecialties. Resp. Ex. I at 2. Dr. Jamieson has also been an ad hoc reviewer for the journal Headache since 2002 and an ad hoc reviewer for Archives of Neurology/JAMA Neurology since 2009. Id. at 3. She is also the headache editor for the Journal of Neuroimaging since 2019. Id. at 4.

While she was an attending physician and until 2018, her major teaching and clinical responsibilities at New York Presbyterian Hospital – Weill Cornell Medicine included caring for patients with headaches. Resp. Ex. I at 4. She regularly lectured on the subjects of diagnosis and treatment of migraines, headache prevention and treatment, and neuroimaging in headache

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<sup>37</sup> Dr. Jamieson submitted five expert reports and testified at the hearing. Resp. Exs. A, C, D, G, K; Tr. 3.

disorders. Id. at 4-10. Her publications also included the subject of headaches, including a book on headaches used as a study guide for the headache medicine board certification examinations. Id. at 10-14; Tr. 119.

### b. Diagnosis Opinion

Dr. Jamieson disagreed that Petitioner had tension-type headaches<sup>38</sup> or NDPH and opined that Petitioner's predominant complaints were "neck and shoulder pain, not headaches." Resp. Ex. A at 4. Dr. Jamieson explained that Petitioner's neck and shoulder complaints "mirror her pre-vaccinations complaints of shoulder and radicular arm pain," noting her prior shoulder surgery. Id.; see also Tr. 125. Additionally, Petitioner was "injured in a motor vehicle collision and had symptoms of cervical spine disease." Resp. Ex. A at 4.

If a headache disorder were to be considered, Dr. Jamieson opined the appropriate diagnosis would be "cervicogenic headaches," based on Petitioner's complaints and MRI findings showing cervical spondylosis.<sup>39</sup> Resp. Ex. A at 4; Tr. 126. Cervicogenic headaches are "defined by the Headache Classification Committee of the International Headache Society (IHS), The International Classification of Headaches Disorders 3<sup>rd</sup> edition (ICHD-3) 2018 as [] headaches 'caused by a disorder of the cervical spine and its component bony, disc and/or soft tissue elements, usually but not invariably accompanied by neck pain.'" Resp. Ex. A at 5 (quoting Resp. Ex. A, Tab 3 at 150).<sup>40</sup>

Dr. Jamieson disputed Dr. Kinsbourne's proposed diagnosis of tension headache or NDPH because the medical records do not support these diagnoses and Petitioner's treating physicians did not reach either of these diagnoses. Resp. Ex. A at 5. Petitioner's 2017 MRI showed "cervical degenerative disc disease involving the cervical spinal column and the foramina<sup>[41]</sup> through which the cervical nerves exit." Id. Dr. Jamieson opined that Petitioner's neck and shoulder pain are consistent with her MRI findings, especially given her "physically

<sup>38</sup> Petitioner's experts use the phrase tension headaches, which Dr. Jamieson stated is an old term, reflecting an older belief that headaches were due to muscle tension. Tr. 131. These headaches are now called tension-type headaches. Id.

<sup>39</sup> Cervical spondylosis is a "degenerative joint disease affecting the cervical vertebrae, intervertebral disks, and surrounding ligaments and connective tissue, sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots." Cervical Spondylosis, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=107846> (last visited Apr. 22, 2025).

<sup>40</sup> Headache Classification Committee of the International Headache Society (IHS), The International Classification of Headache Disorders, 3rd Edition, 38 Cephalgia 1 (2018).

<sup>41</sup> Foramina refers to "a natural opening or passage, especially one into or through a bone." Foramen, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=19027> (last visited Apr. 22, 2025).

demanding job as a housekeeper.” Id. Moreover, the diagnosis and treatment after vaccination in 2016 was “directed toward pain in her neck and shoulders, not headaches.” Id.

As explained by Dr. Jamieson, cervicogenic headaches are secondary headaches that usually occur with neck pain. Resp. Ex. A at 6. The ICHD-3 (2018) set forth diagnostic criteria for cervicogenic headaches:

- A. Any headache fulfilling criterion C
- B. Clinical and/or imaging evidence of a disorder or lesion within the cervical spine or soft tissues of the neck, known to be able to cause headache
- C. Evidence of causation demonstrated by at least two of the following:
  - 1. headache has developed in temporal relation to the onset of the cervical disorder or appearance of the lesion
  - 2. headache has significantly improved or resolved in parallel with improvement in or resolution of the cervical disorder or lesion
  - 3. cervical range of motion is reduced and headache is made significantly worse by provocative maneuvers
  - 4. headache is abolished following diagnostic blockade of a cervical structure or its nerve supply
- D. Not better accounted for by another ICHD-3 diagnosis.

Id. (quoting Resp. Ex. A, Tab 3 at 150-51).

Next, Dr. Jamieson opined NDPH is a “chronic primary headache syndrome, defined solely by its temporal profile as a persistent headache, occurring daily from an onset that is clearly remembered.” Resp. Ex. A at 7. The ICHD-3 (2018) diagnostic criteria for NDPH requires the headache to (1) have a “[d]istinct and clearly remembered onset, with pain becoming continuous and unremitting within 24 hours,” (2) be present for at least three months, and (3) “[n]ot [be] better accounted for by another ICHD-3 diagnosis.” Id. (quoting Resp. Ex. A, Tab 3 at 55). It is an umbrella diagnosis for a “wide array of different chronic primary headaches of unknown cause, whose only identifying characteristic is specified by a temporal profile defined by headache onset and duration.” Id. at 7-8, 10. “The primary headache types . . . associated with NDPH are migraine and tension-type headaches, neither of which have been associated with an immune-mediated vaccination trigger.” Id. at 9. She agreed the pathogenesis of NDPH is not known and opined there is no support for the idea that this type of headache is caused by the Hep B vaccination. Tr. 136-37.

Further, Dr. Jamieson opined that cervicogenic headaches are not caused by vaccines and “do[] not have any association with infectious or immune mediated disorders.” Resp. Ex. A at 6; see also Tr. 129. Tension-type headaches are very common. Resp. Ex. A at 6. The causal mechanism is not known but may involve “central and peripheral pain mechanisms.” Id. The ICHD-3 (2018) also set forth diagnostic criteria for chronic tension-type headaches:

- A. Headache occurring on  $\geq 15$  days/month on average for  $>3$  months ( $\geq 180$  days/year), fulfilling criteria B–D
- B. Lasting hours to days, or unremitting

- C. At least two of the following four characteristics:
  - 1. bilateral location
  - 2. pressing or tightening (non-pulsating) quality
  - 3. mild or moderate intensity
  - 4. not aggravated by routine physical activity such as walking or climbing stairs
- D. Both of the following:
  - 1. no more than one of photophobia, phonophobia or mild nausea
  - 2. neither moderate or severe nausea nor vomiting
- E. Not better accounted for by another ICHD-3 diagnosis.

Id. at 7 (quoting Resp. Ex. A, Tab 3 at 37).

In summary, Dr. Jamieson opined that Petitioner had preexisting “shoulder and radicular upper extremity symptoms, [and] complained of neck and shoulder pain . . . for about [six] months after two [Hep B] vaccinations . . . . Her neck and shoulder pain did not fit the diagnostic criteria for tension-type headache or NDPH.” Resp. Ex. A at 10. Presuming Petitioner had “any type of headaches accompanied by neck pain,” the diagnosis would be “cervicogenic headaches.” Id.

Regarding Petitioner’s records from Dr. Shah in 2020, and Dr. Kinsbourne’s supplemental report related to the subject of migraine headaches, Dr. Jamieson offered the following opinions. See Resp. Ex. C; Resp. Ex. G (citing Pet. Ex. 33). She agreed with Dr. Shah that Petitioner had chronic migraine headaches in 2020, and opined they were unrelated to her prior vaccinations. Resp. Ex. C at 2. Dr. Jamieson explained that patients with headaches “frequently have multiple different types of headaches.” Resp. Ex. G at 2. Thus, a patient like Petitioner with a history of cervicogenic headaches may also have headaches that fit the diagnostic criteria for chronic migraines. Id.

The ICHD-3 diagnostic criteria for migraines (without aura) require

- A. At least five attacks fulfilling criteria B-D
- B. Headache attacks lasting 4-72 hours (when untreated or unsuccessfully treated)
- C. Headache has at least two of the following four characteristics:
  - 1. unilateral location
  - 2. pulsating quality
  - 3. moderate or severe pain intensity
  - 4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)
- D. During headache at least one of the following:
  - 1. nausea and/or vomiting
  - 2. photophobia and phonophobia
- E. Not better accounted for by another ICHD-3 diagnosis.

Resp. Ex. G at 2 (quoting Resp. Ex. A, Tab 3 at 18-19). The ICHD-3 defined chronic migraines as a “[h]eadache occurring on 15 or more days/month for more than three months, which on at least eight days/month, has the features of migraine headache.” Id. at 3 (quoting Resp. Ex. A, Tab 3 at 24).

In her affidavit, Petitioner averred she had headaches three to four times per week. Resp. Ex. G at 3 (citing Pet. Ex. 13). Dr. Jamieson noted this is consistent with the frequency noted in the definition of chronic migraines. Id. She explained that “[t]he characteristics of a migraine headache may change daily, and chronic migraine may have both migraine-like and tension-type-like characteristics,” however, “[a]s long as the headache that occurs more days than not has migraine-like clinical characteristics for at least eight days a month, the headache diagnosis is chronic migraine.” Id. Dr. Jamieson reiterated her opinion that Petitioner’s vaccinations did not play a role in causing Petitioner’s headaches. Id.

Dr. Jamieson’s final expert report addresses Dr. Bodor’s opinions related to tension-type headaches presented at the hearing. See Resp. Ex. K at 1-2. She stated that Dr. Bodor used “outdated nomenclature” (“tension headaches” or “tension-migraines”) which “inaccurately simplified” tension-type headaches and its pathophysiology. Id. at 2; Tr. 131-34. In support of her opinions, Dr. Jamieson cited to a Table from Onan et al.<sup>42</sup> that illustrated the difference between tension-type headaches and migraines:

**Table 1** Clinical features of migraine and TTH

	Migraine	TTH
Lateralization	Unilateral (60%)	Bilateral
Headache characteristics	Pulsatile	Pressing
Duration	4-72 h	30 min-24 h
Severity	Moderate to severe	Mild to moderate
Aggravated by normal physical activity	+	-
Nausea or Vomiting	Common	Mild nausea in CTTH
Photophobia, Phonophobia or Aura	Common	Typically not accompanied

*TTH* Tension-type headache, *CTTH* Chronic tension-type headache

Resp. Ex. K at 3 (citing Resp. Ex. K, Tab 1 at 5 tbl.1).

### c. Causation Opinion

Regardless of the specific diagnosis, Dr. Jamieson opined that there is no causative relationship between Petitioner’s vaccinations and her headaches. Tr. 141. She agreed that Petitioner had a reaction to her second Hep B vaccination reflecting “acute/subacute reactogenicity symptoms” and a headache can be part of that reaction, however, these were mild transient symptoms lasting only a few days. Tr. 143. Dr. Jamieson attributed Petitioner’s ongoing pain and chronic symptoms to her preexisting and symptomatic cervical spondylosis. Tr. 148-49.

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<sup>42</sup> Dilara Onan et al., Debate: Differences and Similarities Between Tension-Type Headache and Migraine, 24 J. Headache & Pain 1 (2023).

Dr. Jamieson disputed that NDPH are caused by vaccinations. Resp. Ex. A at 9-10. She opined that tension-type headaches, NDPH, and cervicogenic headaches are not associated with vaccinations, including those administered to Petitioner. Id. While she agreed that “[s]pecific primary headache types may be associated with triggers for each individual headache occurrence,” that association does not extend to the “onset of the entire disease entity.” Id. at 8. For example, an episode of migraine may be triggered by weather changes, stress, hunger, or drinking red wine, or it may occur without any trigger at all. Id.

She explained that while NDPH is a primary chronic headache generally associated with a retrospective event, a temporal association does not prove causation. Resp. Ex. A at 8. For example, a 2016 study from Rozen<sup>43</sup> of 97 patients with NDPH noted that although many triggering events were suggested, 53% of their patients did not report a triggering event. Id. (citing Resp. Ex. A, Tab 8 at 1). Dr. Jamieson explained that although the list of triggers is expanding, NDPH is an “unexplained event” which is “common in medicine in general and headache medicine in particular.” Id. at 9. Further, tension-type headaches and migraines are associated with NDPH, but these have not been associated with an immune-mediated trigger or vaccination. Id. She was unable to find any medical literature describing a cause and effect association between NDPH, cervicogenic, or tension-type headaches and vaccination. Id. at 9-10.

In response to Dr. Kinsbourne’s citation to a case report where the HPV vaccination allegedly triggered NDPH, Dr. Jamieson determined details were lacking. Resp. Ex. A at 9 (citing Pet. Ex. 17 at 3; Resp. Ex. A, Tab 7 at 2;<sup>44</sup> Resp. Ex. A, Tab 10 at 4).<sup>45</sup> Due to the lack of detail, and the fact that NDPHs have numerous triggers, Dr. Jamieson opined that without more information, these cases did not provide proof of causation. Id.

Dr. Jamieson also briefly reviewed proposed mechanisms for NDPHs, including infection and elevated TNF- $\alpha$  in the cerebrospinal fluid, and explained the problems with these theories. Resp. Ex. A at 10. She concluded that “[t]here [was] no evidence, either epidemiological or biomechanistic, of a causal or triggering relationship between [the headaches at issue herein] and vaccination.” Id.

In her second expert report, Dr. Jamieson addressed Petitioner’s 2020 medical records from neurologist Dr. Shah, who diagnosed Petitioner with chronic migraines. Resp. Ex. C at 2. Dr. Jamieson agreed with Dr. Shah’s diagnosis and opined “[t]here is no causal relationship between the neurological diagnosis of migraine, a common neurological disease with headaches

<sup>43</sup> Todd D. Rozen, Triggering Events and New Daily Persistent Headache: Age and Gender Differences and Insights on Pathogenesis—A Clinic-Based Study, 56 Headache 164 (2016).

<sup>44</sup> Todd D. Rozen, The Three T’s of NDPH (How Clinical Observations Have Led to Improved Treatment Outcomes), 59 Headache 1401 (2019).

<sup>45</sup> Todd D. Rozen, New Daily Persistent Headache: Clinical Perspective, 51 Headache 641 (2011).

and associated symptoms [with] [] genetic and trigeminovascular mechanisms without any causative links to vaccinations or deltoid injections.” Id. at 2-3.

Dr. Jamieson’s second report also addressed Dr. Bodor’s opinions. Resp. Ex. C at 2-3. She opined that Dr. Bodor’s proposed mechanism of vaccine-related pain in the deltoid muscles, triggering chronic muscle spasms and leading to chronic neck pain and headaches, is not based on “any mechanical, inflammatory, immunological, vascular, or psychological basis.” Id. at 3.

In her third expert report, Dr. Jamieson addressed preliminary findings in the undersigned’s Rule 5 Order issued in November 2021. Resp. Ex. D (citing 2021 Rule 5 Order). Dr. Jamieson agreed that Petitioner may have experienced a “possible immunization reaction” with ‘muscle tension in her neck and shoulders bilaterally’ after receipt of her vaccines in April 2016. Id. at 2. After her second Hep B vaccination in May 2016, Dr. Jamieson opined Petitioner had “acute reactogenicity symptoms” which were transient and did not cause her chronic shoulder, neck, and head pain (cervicogenic headaches). Id. Instead, Dr. Jamieson explained that Petitioner had “preexisting cervical spine pathology” and “severe cervical spondylosis” which worsened over time due to the aging process, as well as the trauma of motor vehicle accidents that occurred before and after the vaccinations at issue. Id. Dr. Jamieson further explained that although vaccinations can cause transient headaches and muscle pain, they do not cause the type of chronic complaints that Petitioner experienced. Id. at 2-3.

In her final report, Dr. Jamieson briefly explained the “complex pathophysiological mechanisms” of tension-type headaches and migraines to illustrate Dr. Bodor’s “inaccurately simplified description.” Resp. Ex. K. at 2-4. She concluded that Dr. Bodor’s opinion based on inflammation is not supported by current medical literature or the ICHD-3, stating the “role of inflammation in these two . . . disorders has yet to be determined and does not appear to be a significant component of their pathophysiological mechanisms.” Id. at 4-5. Dr. Jamieson also criticized Dr. Bodor’s opinions related to the use of Botox to treat migraines. Id. at 5. She stated that Dr. Bodor’s description of Botox as a “muscle relaxer” was also inaccurate. Id. Botox is used to inhibit “nociceptive activation,” which she described in detail.<sup>46</sup> Id.

#### **4. Respondent’s Expert, Dr. You-Wen He<sup>47</sup>**

##### **a. Background and Qualifications**

Dr. He is currently a Professor of Integrative Immunobiology at Duke University Medical Center. Resp. Ex. H at 1. Dr. He received his M.D. from the Fourth Military Medical University in Xian, China, and his Ph.D. in Microbiology and Immunology from the University of Miami School of Medicine in Miami, Florida. Id. His research areas include “innate and adaptive immunity against viral and bacterial infections[,] as well as tumors.” Resp. Ex. E at 1. He has conducted research on human immune responses to viral infections and is currently a Co-Principal Investigator for clinical trials focusing on cancer immunotherapy. Id. Dr. He has

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<sup>46</sup> For Dr. Jamieson’s discussion of nociceptive activation, see Resp. Ex. K at 4-5.

<sup>47</sup> Dr. He submitted two expert reports and testified at the hearing. Resp. Exs. E, J; Tr. 3.

reviewed National Institutes of Health (“NIH”) studies, serves on editorial boards, and has authored or co-authored numerous publications. Id. at 1-2; Resp. Ex. H at 2-3, 7-18.

### **b. Diagnosis Opinion**

Dr. He did not offer an opinion about Petitioner’s appropriate diagnosis relative to Petitioner’s headaches and deferred to the clinical expert physicians regarding diagnosis. Resp. Ex. E at 5. He explained the types of headaches at issue and offered his opinions about whether such headaches can be caused by the Hep B vaccination. See id. at 3-9.

### **c. Causation Opinion**

#### **i. Althen Prongs One and Two**

Dr. He defined tension-type headaches (formerly known as tension headaches, among other names) as the most common headache reported, with three types based on frequency of headache. Resp. Ex. E at 3 (citing Resp. Ex. E, Tab 1 at 1-2).<sup>48</sup> Chronic tension-type headaches occur 15 days or more per month. Id. (citing Resp. Ex. E, Tab 1 at 2). The cause of this type of headache is not known. Id. (citing Resp. Ex. E, Tab 1 at 3 (“The pathogenesis of [tension-type headaches] is probably multifactorial, but the precise mechanisms are uncertain.”)). But “peripheral activation or sensitization of myofascial nociceptors”<sup>49</sup> are thought to play an important role. Id. (quoting Resp. Ex. E, Tab 1 at 3). Further, “sensitization of pain pathways in the central nervous system [(“CNS”)] due to prolonged nociceptive stimuli from pericranial myofascial tissues may be responsible” for converting episodic tension-type headaches into chronic tension-type headaches. Id. (quoting Resp. Ex. E, Tab 1 at 3). Genetic factors, heightened sensitivity, stress, and mental tension may all play a role in triggering these headaches. Id. (citing Resp. Ex. E, Tab 1 at 3-5, 8).

Next, Dr. He described chronic daily headaches, a category of headaches that include chronic migraine headaches, chronic tension-type headache, and NDPH. Resp. Ex. E at 3-4 (citing Resp. Ex. E, Tab 2 at 2).<sup>50</sup> NDPH is characterized by “abrupt onset” and this type is usually unremitting. Id. at 4. Some studies have shown an association with infection, and “flu-

<sup>48</sup> Frederick R. Taylor, Tension-Type Headache in Adults: Pathophysiology, Clinical Features, and Diagnosis, UpToDate, <https://www.uptodate.com/contents/tension-type-headache-in-adults-etiology-clinical-features-and-diagnosis> (last updated Nov. 10, 2020).

<sup>49</sup> A nociceptor is “a receptor for pain caused by injury to body tissues; the injury may be from physical stimuli such as mechanical, thermal, or electrical stimuli, or from chemical stimuli.” Nociceptor, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=34163> (last visited Apr. 22, 2025).

<sup>50</sup> Ivan Garza & Todd J. Schwedt, Overview of Chronic Daily Headache, UpToDate, <https://www.uptodate.com/contents/chronic-daily-headache-associated-syndromes-evaluation-and-management> (last updated June 1, 2020).

like illnesses, “extracranial surgery,” or a “a stressful life event” may trigger NDPH, although the majority of patients are unable to identify any precipitating event. Id. (citing, e.g., Resp. Ex. E, Tab 3 at 1-3).<sup>51</sup>

As explained by Dr. He, there is no supporting evidence linking vaccines to NDPH. Resp. Ex. E at 4. He conducted a PubMed<sup>52</sup> search and was unable to find any medical literature associating vaccinations with NDPH. Id. He explained that Dr. Kinsbourne’s statement attributing onset of NDPH two days after a second HPV vaccination (reported by Robbins et al.) was “misleading” due to the lack of information about the patient’s past medical history or comorbidities. Id. at 5 (citing Pet. Ex. 17 at 3). This “one-sentence description of a single patient . . . did not provide evidence that HPV vaccine is a trigger of NDPH.” Id. at 9; see also Tr. 95-96.

While Dr. He agreed infections have been associated with the onset of NDPH, he disagreed with Dr. Kinsbourne’s opinion that vaccination is like infection. Resp. Ex. E at 6. As explained by Dr. He, “infections are fundamentally different from vaccinations in their capability to induce immune responses.” Id. Dr. He explained in detail the differences between the immune system response to an infection as compared to vaccination, noting that infectious pathogens “contain many more components to stimulate a much broader immune response than their corresponding vaccines.”<sup>53</sup> Id.; see also Tr. 97-102.

He also opined that Dr. Kinsbourne’s statement that “[i]nfections and vaccinations share surface epitopes that activate the immune system” is incorrect. Resp. Ex. E at 8-9 (quoting Pet. Ex. 14 at 5). Dr. He explained that the antigenic epitopes of vaccines do not activate the immune system to cause infection. Id. at 9. Instead, the shared “epitopes only serve as ligands for T cell or B cell receptors” and they are not sufficient to activate the immune system to cause infection. Id.

Regarding Dr. Kinsbourne’s causal mechanism based on “a proinflammatory cytokine reaction” that induced “inflammatory changes around the brain,” Dr. He opined it was speculative and lacked evidentiary support. Resp. Ex. E at 8 (quoting Pet. Ex. 14 at 4). Dr. He examined the literature cited by Dr. Kinsbourne and concluded that it did not support a causal role for the Hep B vaccine. Id.

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<sup>51</sup> Ivan Garza & Todd J. Schwedt, New Daily Persistent Headache, UpToDate, <https://www.uptodate.com/contents/new-daily-persistent-headache> (last updated Sept. 23, 2021).

<sup>52</sup> “PubMed is a free resource supporting the search and retrieval of biomedical and life sciences literature . . . . The PubMed database contains more than 38 million citations and abstracts of biomedical literature.” Nat’l Libr. Med., Nat’l Ctr. for Biotechnology Info., PubMed Overview, <https://pubmed.ncbi.nlm.nih.gov/about/> (last visited Apr. 22, 2025).

<sup>53</sup> For Dr. He’s detailed analysis of the differences between how infections and vaccinations activate the immune system, see Resp. Ex. E at 6-8; Tr. 97-102. For the sake of brevity, this testimony is not included in this Decision.

Dr. He explained that Garcia-Oscos et al. did not examine brain inflammation. Tr. 102-03 (citing Pet. Ex. 15). He explained that in this mice study, two types of stress were used: injection of lipopolysaccharide (“LPS”) endotoxin<sup>54</sup> and an electric shock in the foot. Tr. 103; Resp. Ex. E at 8. Then brain tissue was examined to assess changes in synaptic excitation/inhibition. Tr. 103. According to Dr. He, this was not a study about brain inflammation, instead it dealt with synaptic electro current changes. Id. In all, Dr. He opined none of Dr. Kinsbourne’s literature provided evidence to support a causal mechanism between Hep B vaccination and NDPH. Resp. Ex. E at 8 (citing Pet. Exs. 15-16, 18-19); Tr. 103-04.

After responding to Dr. Kinsbourne’s opinions, Dr. He turned to Dr. Bodor’s proposed theories. Dr. Bodor suggested a “possible mechanism” based on “nonspecific inflammation” which “could have made [Petitioner’s] neck stiff . . . . The inflammation from the vaccinations could have started a cycle of muscle tightness and stiffness, and that in the right person it started this cycle of tension migraines.” Resp. Ex. J at 1-2 (quoting Tr. 19-21). Dr. He had several criticisms of this theory. Id. at 2. First, he explained Dr. Bodor failed to use accurate immunological terminology when describing nonspecific inflammation. Id. “[N]onspecific inflammation should have been described as the activation of the innate immune system . . . .” Id. Dr. He explained that “nonspecific inflammation, the activation of innate immunity, [] occurs in all vaccinees.” Id. Thus, if this theory were correct, there would be “extensive clinical evidence” showing that vaccinations are associated with tension headaches; however, such evidence is lacking. Id.

Dr. He’s next criticism focused on Dr. Bodor’s opinion that the flu infection can cause symptoms like stiffness of the neck, which can trigger tension headaches. Resp. Ex. J at 2. This conclusion “reflects a lack of understanding [of] the fundamental differences” between infection and vaccination. Id. As explained earlier when responding to Dr. Kinsbourne’s opinions, Dr. He summarized the differences between immunological responses to infections versus vaccinations. Id. In summary, “[t]he process of infections cannot be controlled while vaccinations are [a] highly controlled process. The fact that flu or other viral inflammatory diseases cause stiffness of the neck is due to much stronger immune activations by infections” and “[t]here is no evidence . . . that the vaccines [Petitioner] received can cause stiffness of the neck.” Id. Dr. He agreed that vaccines cause an inflammatory response and that an inflammatory response can cause pain. Tr. 115. He also agreed that people have different immune responses. Id.

When asked during cross-examination whether he agreed with Petitioner’s physicians’ decision to withhold the third Hep B vaccination, Dr. He agreed that it was appropriate to decline to administer it “out of caution.” Tr. 113. Dr. He also agreed that Petitioner had a transitory

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<sup>54</sup> Endotoxins are “a heat-stable toxin associated with the outer membranes of certain gram-negative bacteria” and “are not secreted but [] released only when the cells are disrupted; they are less potent and less specific than the exotoxins; and they do not form toxoids.” Endotoxin, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=16440> (last visited Apr. 22, 2025). Endotoxins “are composed of complex lipopolysaccharide molecules.” Id. “When injected in large quantities the endotoxins produce hemorrhagic shock and severe diarrhea; smaller amounts cause fever, altered resistance to bacterial infection, leukopenia followed by leukocytosis, and numerous other biologic effects.” Id.

adverse reaction to her second Hep B vaccination, characterized by muscles spasms, low grade fever, and headache. Tr. 113-14. But he disagreed that vaccines can or did cause Petitioner's tension-type headaches. Tr. 117. He also testified that transitory pain is not the same as permanent injury or damage. Tr. 116-17. Similarly, he opined that a "transitory immune response and transitory cytokine production," with local transitory inflammation, does not cause tension-type headaches. Tr. 117.

Dr. He concluded that "to a reasonable degree of medical certainty that there is no reliable evidence to support [] [P]etitioner's experts' theory that the [Hep] B vaccine might have caused [Petitioner's] NDPH." Resp. Ex. E at 9. He also opined that there is no evidence that the Hep B vaccination can "cause a tension type headache." Tr. 93, 104.

## ii. Althen Prong Three

Dr. He agreed that Petitioner's "syndrome ha[d] a temporal relation" with the receipt of her Hep B vaccination. Resp. Ex. E at 8. However, because "there is no relevant case report/study on vaccination and NDPH," Dr. He opined that "it is not possible to determine what constitutes a medically reasonable interval between vaccination and disease onset." Id. at 9.

## III. DISCUSSION

### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d

at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a *prima facie* case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a *prima facie* case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether *prima facie* showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

## B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell ex rel. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at \*19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)).

Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at \*3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at \*3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (noting Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

### C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatman v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

#### IV. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since “each prong of the Althen test is decided relative to the injury [,]” determining facts relating to the claimed injury can be significant. Id. Here, the parties disagree as to diagnosis. Petitioner offers two diagnoses, chronic tension headaches and/or NDPH. Respondent’s neurologist expert disagrees that Petitioner’s complaints were headaches. Instead, she complained of neck and shoulder pain. Moreover, she was not diagnosed with headaches until 2020, when she was diagnosed with migraines.

Based on the facts presented, the undersigned finds that preponderant evidence supports a finding that after her initial Hep B vaccination on April 6, 2016, Petitioner had muscle tension bilaterally of the neck and shoulders. She did not, however, complain of a headache. While “possible immunization reaction” was considered, that diagnosis was provided in terms of a possibility only. There is no evidence that any health care provider diagnosed a “probable” immunization reaction or headache. Pet. Ex. 2 at 9-10. And testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman, 123 Fed. Cl. at 573-74.

On May 18, 2016, Petitioner returned for her second Hep B vaccination, and at that visit, she complained of persistent residual cervical spine stiffness, but it was “much less” than before. Pet. Ex. 2 at 11. Her end ranges of cervical flexion, extension, and rotation were “stiff.” Id. Petitioner did not complain of headache. The following day, May 19, Petitioner continued to have cervical spine musculature problems, and she was diagnosed with an adverse reaction to the vaccine. She was not able to return to work due to “rigor/muscle spasm.” Id. at 12. Petitioner did not complain of headache.

There are a few references to headache in Petitioner’s medical records in the two-year period after her Hep B vaccinations in April and May 2016. The first reference was at a PT visit on May 24, 2016. Petitioner reported a headache in the back of her head when sitting up and in the frontal aspect when lying down. She also reported moderate headaches which “come

frequently.” Pet. Ex. 4 at 2. Diagnosis and treatment at that visit was for neck pain. There was no diagnosis of headache.

Shortly after that PT visit, at follow-up visits with Dr. Gopang on May 27 and June 29, there was no mention of headache. On June 6, when Petitioner returned to Carroll County Occupational Medicine, there was no documentation of headache.

Petitioner first saw Dr. Duplechan, a physical medicine specialist, on July 6, 2016. At the initial visit, a detailed history was documented. Petitioner reported severe neck pain, but there is no evidence she reported headache. Diagnosis was cervical myofascial pain, not headache. Review of systems was negative for neurological conditions.

When Petitioner returned to Dr. Duplechan on October 12, there was no reference to headache.

The second documentation of headache was six months after her first Hep B vaccination on October 25, 2016, again in a PT note. Petitioner reported she had “headaches almost all the time” although they did not prevent her from working. Pet. Ex. 24 at 9. However, headaches were not reported at the following PT visits on October 27, 28, or 31.

On February 14, 2017, Petitioner saw Dr. Gopang, where she again complained of recurring neck and back pain. The records do not document headaches.<sup>55</sup> Review of systems noted “No Chronic Headaches” and neurological review of systems stated, “No Frequent Headaches.” Pet. Ex. 3 at 13-14. However, the records include a comment stating, “pain in neck and headache.” Id. at 14.

In her affidavit, executed December 6, 2019, Petitioner averred that the vaccinations she received on April 6, 2016 caused a headache, and that she continued to have headaches for eight months. And, as of the date of the affidavit, she continued to have headaches three to four days per week. However, this testimony contrasts with the many visits to physicians and health care providers, where headache is not referenced, or where the records specifically state no headaches.

Because Petitioner’s affidavit is inconsistent with and contradicted by the contemporaneous medical records of multiple treating physicians, the undersigned finds it reasonable to give greater weight to the contemporaneous medical records. See Cucuras, 993 F.2d at 1528 (noting that “the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight”); Doe/70 v. Sec’y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010); Stevens v. Sec’y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at \*3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that “clear, cogent, and consistent testimony can overcome such missing or contradictory medical records”); Vergara

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<sup>55</sup> On February 28, 2017, Petitioner underwent a cervical spine MRI. Indication was for “chronic worsening neck pain and stiffness with posterior headaches following her [second] [Hep B] shot.” Pet. Ex. 3 at 16. It is not clear whether the radiology staff or the ordering physician (Dr. Gopang) wrote this statement.

ex rel. J.A.V. v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at \*4 (Fed. Cl. Spec. Mstr. May 15, 2014) (“Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.”).

In the two-year period after the vaccinations at issue, Petitioner had numerous visits to multiple physicians and other health care providers.<sup>56</sup> In all these visits, there are a few occasions where she complained of headaches to PT providers and one physician. But the majority of her visits do not support a finding that Petitioner had headaches. Further, she was never given a headache-related diagnosis. The physicians and health care providers did not attribute her headaches to vaccination. Given the totality of the contemporaneous medical record evidence, the undersigned finds that Petitioner has not proven by preponderant evidence that she suffered a vaccine-related headache disorder as asserted by her experts.

Moreover, the undersigned finds Dr. Jamieson’s opinions more persuasive as they align with the facts and physician diagnoses in the Petitioner’s medical records. Dr. Jamieson disagreed that Petitioner had a headache disorder. She opined that Petitioner’s predominant complaints were neck and shoulder pain, not headaches. The undersigned agrees with Dr. Jamieson that Petitioner’s primary complaint related to her neck and shoulder pain, not headaches.

Moreover, Petitioner failed to show that the diagnosis of migraine headaches by Dr. Shah in 2020 establishes preponderant proof that she had migraine headaches in 2016 after her vaccinations. She failed to offer preponderant evidence that a diagnosis four years after the fact, with an intervening motor vehicle accident, is relevant or could be attributed to vaccinations after such a long period of time.

Even if Petitioner had established a headache diagnosis as asserted by her experts, she failed to prove by preponderant evidence a causal theory or logical sequence of cause and effect (Althen prongs one and two) to explain how her Hep B vaccinations can or did cause a chronic headache disorder, regardless of the specific headache diagnosis. Therefore, the undersigned’s Decision regarding entitlement does not turn solely on the question of whether Petitioner has proven a headache diagnosis.

## V. CAUSATION ANALYSIS

### A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how a covered vaccine—Hep B—could have caused a headache. Andreu, 569 F.3d at 1375; Pafford,

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<sup>56</sup> Even after this two-year period, there appears to be only one mention of a history of headaches, and this was on August 1, 2018, after her motor vehicle accident. See Pet. Ex. 26 at 3-4. Subsequently, review of systems and records were repeatedly negative for headache for 2018 to 2020, when she returned to see Dr. Duplechan in May 2020, and then saw Dr. Shah in September 2020. See Pet. Ex. 25 at 4; Pet. Ex. 30 at 2-15.

451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds that Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the Hep B vaccination can cause headaches for the reasons discussed below.

First, regarding Dr. Kinsbourne's opinions, he conceded that the pathology of NDPH and tension headaches is not known. See Pet. Ex. 14 at 4 ("The mechanism of the underlying pathology in NDPH is unknown."). In this context of an unknown mechanism, Dr. Kinsbourne offered two theories of causation. The first appears to analogize vaccinations with infection. But he does not explain how infections cause chronic headaches, nor does he explain how vaccinations can act like infections so as to cause headaches. Instead, he suggests that infections interact with an unidentified susceptibility to trigger a low-level immune reaction. Even then, he does not describe how vaccinations cause an ongoing low-level immune reaction that can cause a chronic headache condition. "An expert may 'extrapolate from existing data,' and use 'circumstantial evidence,' [b]ut the reasons for the extrapolation should be transparent and persuasive." K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at \*12 (Fed. Cl. Spec. Mstr. July 7, 2016) (internal citations omitted) (first quoting Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009); and then quoting Althen, 418 F.3d at 1280). Here, Dr. Kinsbourne failed to explain this mechanism and how it could be extrapolated to the vaccines and injury here.

Dr. Kinsbourne's second theory is based on proinflammatory cytokines, and he suggests that they cause some type of chronic meningeal inflammation or neuroinflammation. But again, he does not explain how vaccinations can cause ongoing low levels of proinflammatory cytokines, or how these would cause a chronic headache condition. The papers he cites do not mention vaccinations, and Dr. Kinsbourne does not explain how the studies or findings referenced relate to or support his theory. As such, Dr. Kinsbourne's theories of causation are unsupported by medical or scientific facts, research, or any other reliable evidence. Moreover, his theories are speculative and/or conclusory in nature. This is not a new issue to Dr. Kinsbourne. See, e.g., LaLonde ex rel. M.L. v. Sec'y of Health & Hum. Servs., No. 06-435V, 2012 WL 5351164, at \*18 (Fed. Cl. Spec. Mstr. Sept. 28, 2012) (finding Dr. Kinsbourne's testimony speculative as he "[was] unable to specifically explain or opine to any of the [] mechanisms he propose[d]"), mot. for rev. den'd, 110 Fed. Cl. 184, 208 (2013) (finding "the special master properly evaluated the credibility of Dr. Kinsbourne's testimony" under Federal

Circuit precedent), aff'd, 746 F.3d 1334 (Fed. Cir. 2014); Conway ex rel. Conway v. Sec'y of Health & Hum. Servs., No. 07-857V, 2011 WL 1167632, at \*12-14 (Fed. Cl. Spec. Mstr. Mar. 7, 2011); Hammitt ex rel. Hammitt v. Sec'y of Health & Hum. Servs., No. 07-170V, 2011 WL 1135878, at \*7 (Fed. Cl. Spec. Mstr. Mar. 4, 2011) (“At best, Dr. Kinsbourne’s testimony . . . was speculative, and speculative testimony does not equate to preponderant evidence.”), aff'd, 98 Fed. Cl. 719, aff'd, 676 F.3d 1373 (Fed. Cir. 2012); Egan ex rel. Gum v. Sec'y of Health & Hum. Servs., No. 05-1032V, 2009 WL 1440240, at \*15 (Fed. Cl. Spec. Mstr. May 1, 2009) (Dr. Kinsbourne’s testimony “requires reliable evidence to support it, not mere words. . . . Dr. Kinsbourne has an obligation as an expert to ground his opinions in good medicine, clinical findings and supportable facts.”).

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject “conclusory expert statements that are not themselves backed up with reliable scientific support.” Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at \*31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. den'd, decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). Special masters are expected to carefully scrutinize the reliability of each expert report submitted. Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at \*19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). The undersigned will not rely on “opinion evidence that is connected to existing data only by the ipse dixit of the expert.” Id.

Second, Dr. Bodor also offers opinions unsupported by facts or evidence. Dr. Bodor’s first proposed mechanism set forth in his expert report was that the pain caused by a Hep B vaccination can trigger pain in the deltoid muscle that can induce spasms in the muscles of the neck. Dr. Bodor did not offer evidence in the way of medical records or medical literature to support this mechanism. Further, he did not opine that this mechanism can lead to chronic headaches. The undersigned finds this opinion conclusory in nature and unsupported by evidence.

At trial, Dr. Bodor offered two mechanisms. The first was that Petitioner had pain in the deltoid muscle and other muscles had to be used to abduct the shoulders. This resulted in an overuse of muscles which triggered pain and tightness that triggered headaches. He further proposed that once this process begins, a cycle of tension headaches begins which persists even after the stimulus had resolved. Again, Dr. Bodor did not offer any medical records or medical literature or other evidence to support this theory. Assuming vaccination could induce an overuse type syndrome from deltoid pain, and that it could trigger chronic headaches, one would expect a reference to it in Petitioner’s medical records or medical literature.

Overall, the undersigned finds Petitioner’s theories here are unsupported by medical or scientific facts, research, or any other reliable evidence and are speculative and/or conclusory in nature. The undersigned will not rely on “opinion evidence that is connected to existing data only by the ipse dixit of the expert.” Prokopeas, 2019 WL 2509626, at \*19. The undersigned finds these statements from Dr. Kinsbourne and Dr. Bodor “conclusory” and “not themselves backed up with reliable scientific support.” Kreizenbeck, 2018 WL 3679843, at \*31.

Simply asserting a causal theory without context or a supportive factual framework based on medical literature, research, or other evidence is insufficient. The causal theory must be specific to the petitioner's case. Moberly, 592 F.3d at 1322. Merely identifying a mechanism for a disease process without additional evidence specific to Petitioner's case is insufficient to preponderantly show causation. See Monzon v. Sec'y of Health & Hum. Servs., No. 17-1055V, 2021 WL 2711289, at \*29 (Fed. Cl. Spec. Mstr. June 2, 2021); Baron v. Sec'y of Health & Hum. Servs., No. 14-341V, 2019 WL 2273484, at \*17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019); Duncan v. Sec'y of Health & Hum. Servs., No. 16-1367V, 2020 WL 6738228, at \*11 (Fed. Cl. Spec. Mstr. Oct. 19, 2020), aff'd, 153 Fed. Cl. 642 (2021); Boatmon, 941 F.3d at 1360; LaLonde, 746 F.3d at 1339 (citing Moberly, 592 F.3d at 1322); W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013).

At the hearing, Dr. Bodor's second "possible mechanism" was based on "nonspecific inflammation" that led to neck stiffness and headaches. Tr. 21. He discussed muscle tension and how that can lead to headaches. But he referred to this as a "possible mechanism." Id. And opinions expressed as possibilities are not sufficient to establish causation. See, e.g., Waterman, 123 Fed. Cl. at 573-74; Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence).

When asked how these mechanisms can cause chronic headaches, Dr. Bodor used the analogy of complex regional pain syndrome or sympathetic pain. However, the injury at issue here is not complex regional pain syndrome or sympathetic pain, and Dr. Bodor did not explain how this analogy was relevant. Further, he explained that the cause of these pain cycles and why they continue and become chronic is not known.

Further, the undersigned finds Respondent's expert Dr. Jamieson and her opinions more persuasive. By virtue of her specialty of neurology and her clinical experience diagnosing and caring for adult patients with headache disorders, as well as writing on the subject, she has more training and experience relevant to the diagnosis and cause of headaches as compared with the other experts. Dr. Kinsbourne was a pediatric neurologist, he did not have a practice caring for adult patients with headaches, and he practiced last in the 1990s. Dr. Bodor is a physical medicine and rehabilitation specialist. While he treats pain, his CV does not show that he has expertise in headaches.

Thus, the undersigned affords more weight to the opinions of Dr. Jamieson. See Koehn v. Sec'y of Health & Hum. Servs., No. 11-355V, 2013 WL 3214877, at \*32 (Fed. Cl. Spec. Mstr. May 30, 2013) ("In weighing the persuasiveness of opinion testimony, special masters may consider the relative expertise of the witness."), aff'd, 773 F.3d 1239 (Fed. Cir. 2014); see also Dwyer v. Sec'y of Health & Hum. Servs., No. 03-1202V, 2010 WL 892250, at \*64 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (giving greater weight to M.D. epidemiologists' opinions on medical issues than to Ph.D. epidemiologist's opinion); Pafford, 451 F.3d at 1359 (affirming the special master's rejection of expert's testimony because he lacked proper qualifications in the specialty areas in which he testified).

Overall, Petitioner has not met her burden as to Althen prong one.

## B. Althen Prong Two

To satisfy Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether Althen prong two is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528 (Fed. Cir. 1993). While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the “diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”).

The undersigned finds that while several of Petitioner’s treating physicians documented opinions that Petitioner had a vaccine reaction, these opinions were related to cervical stiffness and neck pain; none of Petitioner’s treating physicians opined that more likely than not her vaccinations caused or contributed to her chronic headaches.

On April 7, 2016, one day after Petitioner’s first vaccination, she was assessed with muscle tension bilaterally in neck and shoulders and “possible immunization reaction.” Pet. Ex. 2 at 9-10. Headaches were not reported. Between April 7 and May 18, that date on which Petitioner received her second Hep B vaccination, no treating health care provider diagnosed Petitioner with headaches.

On May 19, one day following her second Hep B vaccination, Petitioner complained of muscle spasms and a low-grade temperature. She was diagnosed with “vaccine adverse reaction” and was not allowed to return to work due to “rigors/muscle spasm.” Pet. Ex. 2 at 12-13. Headaches were not reported or documented. Petitioner’s third Hep B vaccination was cancelled. At the next visit, on May 23, Petitioner reported having a stiff neck and was diagnosed with an adverse reaction to Hep B vaccine.

The undersigned finds these records from April 7 to May 23 assess Petitioner with an adverse reaction to vaccination in the context of Petitioner’s complaints of muscle tension and neck pain. Petitioner did not report a headache during these visits. Her treating physicians did not attribute her headaches to vaccinations. Therefore, the undersigned does not interpret the records which note an adverse reaction as opinions by Petitioner’s treating physicians in support a finding that Petitioner’s vaccinations caused her to develop headaches.

Both Dr. Kinsbourne and Dr. Bodor referenced challenge/rechallenge to support vaccine causation. But neither expert identifies the factual underpinnings for their opinions in this regard. After her first Hep B vaccination, Petitioner had muscle tension in her neck and shoulders. There is no evidence in her medical records that she complained of a headache associated with her first Hep B vaccination. After the second Hep B vaccination, Petitioner complained of muscle spasms and a low-grade fever. Again, the medical records do not mention complaints of headaches associated with her second Hep B vaccination. Therefore, there is no factual basis to conclude that Petitioner's headaches were evidence of challenge/rechallenge. She did experience muscle tension and muscle spasms, but because Petitioner did not report headaches after her first vaccination, and Petitioner's alleged injury is a headache, the concept of rechallenge is not supported.

Over the two years following vaccination, Petitioner saw numerous health care providers but reported a headache during very few visits. And at these visits, she was diagnosed with cervicalgia (neck pain), not headache. Petitioner was not given a headache-related diagnosis until 2020, four years after her vaccinations at issue here. Petitioner and her experts did not address the issue or explain how vaccinations or vaccination-induced muscle spasms could cause a migraine/headache four years following administration.

In summary, the undersigned finds that Petitioner failed to provide preponderant evidence of a logical sequence of cause and effect. Thus, Petitioner has failed to satisfy Althen prong two.

### C. Althen Prong Three

Althen prong three requires Petitioner to establish a “proximate temporal relationship” between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a “medically acceptable temporal relationship.” Id. A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged under Althen prong one. Id.; see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542. Thus, prong three contains two parts: first, Petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, they must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

Because Althen prong three coincides with Althen prong one, Petitioner’s inability to meet her burden demonstrating how the Hep B vaccine can cause headaches effectively precludes her from being able to meet her burden under the third Althen prong. Since the undersigned found that Petitioner did not offer a sound and reliable theory of causation, Petitioner cannot demonstrate that her headaches arose in a medically acceptable timeframe pursuant to that theory. Even if Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner’s overall burden of proof. Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a “temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the

vaccine and injury.”). However, Petitioner’s showing with respect to the third Althen prong is deficient.

Petitioner received her first Hep B vaccine on April 6, 2016 and her second Hep B vaccine on May 18, 2016. Petitioner’s experts contend Petitioner’s headaches begin within one day of each vaccination and this timing was medically reasonable. Respondent’s expert Dr. He agreed that Petitioner’s “syndrome ha[d] a temporal relation” with vaccination but opined “it is not possible to determine what constitutes a medically reasonable interval between vaccination and disease onset” due to the lack of literature. Resp. Ex. E at 8-9.

The undersigned finds Petitioner failed to provide evidence to show what a medically appropriate onset of headaches post-Hep B vaccination would be for any of the mechanisms proposed by Petitioner’s experts. Petitioner’s experts also failed to prove by preponderance evidence that her onset of headaches was one day after her Hep B vaccinations. As such, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

Even if Petitioner provided preponderant evidence satisfying Althen prong three, Petitioner cannot prevail since she failed to provide preponderant evidence to prove Althen prongs one and two and a temporal association, without more, is insufficient. Moberly, 592 F.3d at 1323; Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (“[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.”).

## **VI. CONCLUSION**

The undersigned extends her sympathy to Petitioner for the health problems she has suffered. The undersigned’s Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that her vaccinations can and did cause her to develop headaches or any other compensable injury. Therefore, her petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**  
Nora Beth Dorsey  
Special Master